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S. HRG. 103–822

ASSESSING THE EFFECTS OF NASAL RADIUM TREATMENTS

Y 4. J 96/10: S. HRG. 103-822

Assessing the Effects of Nasal Radi...

HEARING

BEFORE THE

SUBCOMMITTEE ON
CLEAN AIR AND NUCLEAR REGULATION

OF THE

COMMITTEE ON
ENVIRONMENT AND PUBLIC WORKS
UNITED STATES SENATE

ONE HUNDRED THIRD CONGRESS

SECOND SESSION

AUGUST 29, 1994

Printed for the use of the Committee on Environment and Public Works

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ASSESSING THE EFFECTS OF NASAL RADIUM TREATMENTS

MONDAY, AUGUST 29, 1994

U.S. SENATE,
COMMITTEE ON ENVIRONMENT AND PUBLIC WORKS,
SUBCOMMITTEE ON CLEAN AIR AND NUCLEAR REGULATION,
Washington, DC.

The subcommittee met, pursuant to notice, at 10:03 a.m. in room 406, Dirksen Senate Office Building, Hon. Joseph I. Lieberman [chairman of the subcommittee] presiding.

Present: Senator Lieberman.

OPENING STATEMENT OF HON. JOSEPH I. LIEBERMAN, U.S. SENATOR FROM THE STATE OF CONNECTICUT

Senator LIEBERMAN. The hearing will come to order. Good morning. I would like to welcome our witnesses and all others who are here this morning.

Today we are going to hear that between the 1940s and the 1960s, tens of thousands of military personnel and civilians were treated with radium nasopharyngeal irradiation to alleviate pressure-related conditions in the ear, and to cure adenoid problems. The treatment involved inserting a rod, tipped with radium, up the nose and leaving it there for several minutes to literally burn out the tissue. A photograph of an Air Force officer patient undergoing the treatment is right over there; it's an actual photograph, you can see it's an older photograph. It illustrates how the treatment was performed.

On the other stand is a cross-section through the head, with the radium-tipped rod inserted into the nose. You can see that the radium capsule is in the nasopharyngeal cavity, near the lower brain, as well as near the thyroid and the pituitary glands.

If a doctor today told a parent—certainly this parent, or any parent I know—that he was going to stick a probe, tipped with radioactive material, up his or her child's nose to burn out some tissue near the child's brain, I can't imagine any parent saying, "Go right ahead, do it." To me, the best evidence of the danger of this radium treatment is the fact that no doctor in his right mind would think of performing such a procedure today.

But we're dealing with an earlier time in this story, when radium was not feared, and many thousands of children did undergo this treatment. The procedure, really, was like an "atomic-age blood letting," with the cure worse than the disease.

It is our job now to correct mistakes of the past and do all we can to warn and treat the former patients whose health and/or lives may now be at risk.

I have been told that this treatment was not pleasant, but our main concern here today, and the concern that I've heard from many people who have undergone this treatment or have been concerned about those who have, is the possibility that the treatment may pose grave health risks.

A number of people who received the radium treatment later developed cancer where the radium came in contact with their body. We need to find out if the radium caused the cancer, and we also need to get the word out to all those who received the treatment to visit their doctor and be examined for any possible ill effects.

I hope that this hearing this morning will focus attention in the problem and lay the groundwork for assuring that the effects of the treatment are studied, and lead to the Government agencies involved releasing medical alerts to those treated, that there may indeed be health problems from the radiation treatment.

From the few studies that have been conducted on treated individuals and from anecdotal evidence provided by former patients across the country, it appears that there are reasons to be seriously concerned about nasopharyngeal irradiation. But the effects of the treatment still need to be scientifically studied. Many thousands of individuals underwent this treatment 20 to 40 years ago, and if there are harmful health effects, they may well be appearing now. That is why it is so important to get the word out to former radium treatment patients: "Let your doctor know that you had the treatment so he or she can determine if you have any ill effects."

The word also must go out to doctors around the country so that they can learn about the history of radium treatments and the potential effect of those treatments on their patients.

This hearing is obviously one way to educate the public and the profession. But again, I hope the Federal Government will do even more to alert doctors and former radium treatment patients.

I particularly want to acknowledge the dedication and hard work of Stewart Farber, who is with us today, who first brought the problem to my attention earlier this year. Since then I've written to Secretary Jesse Brown of the Department of Veterans Affairs, requesting that the department examine nasal radium treatment, conduct a study, and provide information and medical assistance to veterans who are suffering health problems that they attribute to this treatment.

I want to commend Secretary Brown and the VA for at least beginning to look into this issue. The next step now is for the VA to initiate a public health study of veterans who had treatment.

I worked to include language in the 1995 VA/HUD appropriations report that urges the Secretary to initiate just such a study. But as I have noted, many civilians also underwent radium treatments. One published estimate is that it may be as high as 400,000 people, and most of them were children. To really understand any possible latent health effects from the treatment, an epidemiological study must include representatives of the civilian group. Earlier this year I wrote to Secretary Donna Shalala about this issue, and she replied that the Centers for Disease Control could undertake such a study, but would need to locate individuals who were treated, commonly a time-consuming and costly process.

I hope that we will hear today how the CDC can become involved here, and become involved more quickly. Because of the diligent data-gathering efforts of the Submarine Survivors Group, founded by Jim Garrity and Stewart Farber, the VA— with the help of the Department of Defense and the CDC—may now be able to locate many treated individuals in a timely and cost-effective manner.

I want to commend Stewart and Jim for establishing and operating this hotline, which has provided people with information and assistance. It has consumed a lot of their time and, from what I gather, a lot of their resources as well. Their dedication to helping others is really an inspiration.

I am told by this survivors group that the hotline has received calls from over 54,000 individuals who say they underwent this treatment and are concerned about existing or potential effects on their health. Of course, they have a right to know if nasopharyngeal irradiation could result in disease for them. The knowledge is crucial; actually, the knowledge can be the difference between life and death for them.

There is a Connecticut resident who, unfortunately, could not be here with us in Washington today because of his illness, who received this radium treatment, who recently went to his doctor for a checkup after reading a newspaper article about the potential health effects of the treatment. Regrettably, the doctors discovered that he had thyroid cancer, and he is currently undergoing treatment. We hope that the cancer was caught early enough to treat it effectively. But without an awareness that there might be a problem, which he gained from reading about the work of the survivors group here, this man would not have discovered the problem until even later, when it would have been even harder to treat.

Last week, responding to a letter that I sent to them, a member of the White House Human Radiation Working Group told a member of my staff that the working group had considered this problem and is very concerned about the potential effects of these radiation treatments. They also agreed that this is a subject that warrants further investigation. That acknowledgement is important to me, because we really need to have the Departments of Defense, Veterans Affairs, and Health and Human Services working together to address the health concerns of veterans and civilians about nasopharyngeal irradiation treatments.

This hearing is about openness and trust and treatment. It's not about blame. A large number of people underwent a treatment that physicians would not perform today, but today we must make sure, knowing this, that the institutions that performed these treatments are open about what was done. We need an unbiased epidemiological study of the long-term health effects of radium treatment. Then we need to provide those individuals who underwent such treatments with honest, reliable information about any health effects that they face.

I am very grateful to the witnesses who are here today and I look forward to their testimony. I do want to indicate for the record that though my colleague from Rhode Island, Senator John Chafee, could not be here today, he has been active with me on this issue.

Residents of Rhode Island, and especially the veterans who live there, should be aware of his efforts.

And now we will go to the witnesses and begin, if I might, with Dr. Ducatman.

Thank you for being here. We look forward to your testimony.

STATEMENT OF ALAN M. DUCATMAN, M.D., DIRECTOR, INSTITUTE OF OCCUPATIONAL AND ENVIRONMENTAL HEALTH, UNIVERSITY OF WEST VIRGINIA

Dr. DUCATMAN. Thank you, Senator Lieberman. My name is Alan Ducatman. I'm an internist and occupational physician. I am a Professor of Medicine at West Virginia University and Director of the Institute for Occupational and Environmental Health there.

From 1983 to 1986 I was a Lieutenant Commander at the U.S. Navy's Environmental Health Center. Those were by far the best professional years of my life, certainly the most productive. I worked with the finest and most dedicated colleagues imaginable. When I left I was given a medal for investigating similar—different, but similar—episodes of exposures and outcomes. We never tried to say that something was too difficult or too hard to do; we just went and did it.

I left the Navy to go to Massachusetts Institute of Technology, where I had another wonderful job and a lot of fun. Sometime in about 1989 or 1990, I'm not sure exactly when, Stewart Farber came to me at the end of a lecture and he said, "I have a story. I want to check it with you." He told me this extraordinary story about the nasopharyngeal radium treatments. He asked me if I thought it was worthy of study. He gave me a lot of information about them, and I went home and I began to read and I followed up on what he had given me.

The treatment basically consists, as you mentioned, of the insertion of a small probe into the nasopharynx, the back of the mouth, through the nose, for the purpose of shrinking the lymphoid tissue around the opening of the Eustachian tube. It was thought to effectively prevent barotrauma in submariners who went through dunk tank exercises, and in pilots.

Senator LIEBERMAN. Mr. Garrity will describe the dunk tank exercise in a moment, because that is what he was involved in.

On the military side it was the submariners who went through that tank experience, and then Air Force pilots as well?

Dr. DUCATMAN. Correct.

Senator LIEBERMAN. And for which pilots was it used, to the best of your knowledge?

Dr. DUCATMAN. In the pilots it's less clear who got it because there is less documentation in the open literature, but it appears also to be pilots who suffered Aerotitis, Aerotrauma, after going through the changes that one gets in high-performance aircraft.

After reviewing the things that Mr. Farber gave me I told him yes, that this should be brought to public attention; yes, these individuals should be studied. And I gave him some reasons which we then wrote down in a letter to the New England Journal, which we coauthored in 1990.

The reasons I gave him have not changed. The first and most important reason is that we don't know if excess head and neck disease has resulted from the very substantial local dose of radiation that has to be given to accomplish the task. It is quite possible—but not known—that excess disease could have resulted in the local area. Several studies in existence are too small to definitively answer the question. Although one of them raises some interesting questions, none give an answer. Definitive study is needed.

Second, I noted that with the Navy population, even if we took the minimum assumptions, which we did in our letter, was probably large enough to do an effective study. Combined with the Air Force population, the size of which we really did not know because it's less well documented in the open literature, I was quite certain that a large enough population of just military-treated individuals existed to do an effective study.

Third, as has already been mentioned, this is a substantial dose which could conceivably cause some harm. I will let Mr. Farber characterize the dosage.

Fourth, I thought the data were important. They could characterize the outcome at an exposure dose where it had not yet been well done, and they would be important to the understanding of radiation health effects for individuals outside the military.

Fifth, as you have noted, Senator Lieberman, the treatments are no longer acceptable for the purposes used. We just don't do that any more. Review articles disavowing that use appeared beginning in the 1950s.

Senator LIEBERMAN. Let me stop you there. Articles disavowing the use of this treatment began to appear in the 1950s?

Dr. DUCATMAN. That's correct.

And finally, military populations received these treatments as an integral part of their service. They were not experiments, at least not as I see them, but they were also not health care for the usual reasons. They were health care for operational reasons, and I felt therefore that these individuals were owed something special.

Our letter was published by the New England Journal substantially later in 1992, with a letter from the U.S. Navy alongside of it. Understanding of our letter came slowly and was complicated by some irrelevant confusion with much smaller doses in shipyards, where the dose is a tiny fraction as large, and with unsubstantiated prejudgments about absence of excess risk.

A unique aspect of these physician-driven exposures— you might say iatrogenic exposures—is that we can model and determine the exposure level fairly well. Individuals are either treated or not treated, and for those individuals who are treated, we can figure out what their exposure level is with a reasonable degree of certainty through modeling, which you will probably hear about from other individuals in the room. Therefore it is an appropriate and doable thing to study it.

When we wrote the letter in 1990, and when it was published in 1992, I made no prejudgment about a study outcome. I did not—and still do not—know if excess disease would be found if we did a large, excellent study. I want to emphasize that point. What we do not know is the answer; that is the reason to do a study. I make no prejudgment about whether there is excess disease.

Of concern, a small study has found a small excess. That is a question; it is not an answer. I do not know if a larger study will show excess disease, and frankly, I don't think anyone else knows, either.

To obtain good answers, the study must be done to the highest attainable standards of epidemiologic excellence. That implies identification and accurate confirmation of exposed populations in the military, and if we study other populations, outside as well. Experts from several different disciplines need to be involved. We could catalog the types of experts, if that's necessary.

Ideally, appropriate Federal agencies—including, as you have mentioned, the Centers for Disease Control and their National Institute of Occupational Safety and Health—should be involved; perhaps the National Cancer Institute; perhaps the National Institute of Environmental Health Science. All of these Federal agencies have insights that would be helpful.

Certainly, Capitol Hill is not the best place for the language of epidemiology, but I would tell the committee that, yes, this will be a hard study to do. There are many potential biases that go into this type of study, particularly if we're going to look at the common outcomes, such as thyroid disease, that might be of concern. For the less common outcomes, such as nasopharyngeal cancer, the biases will be less important.

The committee should understand that it is hard, but I would point out that I don't think it is impossible. Using data already collected by the Submarine Survivors, it should be possible to perform a fine feasibility study, demonstrating whether or not a designed study can be conducted. Independent, expert panels are certainly appropriate for this type of mission and should be convened, providing that the normal temporal effect of time on veteran mortality is kept in mind. If we intend to include living World War II veterans in the study population, we should not delay indefinitely.

Finally, I bring to you a partly nonscientific observation. Preliminary proof that this group of exposed individuals can be studied has not come from scientists. It hasn't come from people like me at all. It has come from the veterans themselves, who have done rather extraordinary work, which is not surprising. They won the battles of the Atlantic and the Pacific, and they planted the seeds that undermined the wall across Europe. I certainly wouldn't want to tell them that we can't do a good epidemiologic study because it's just not true. We just have to decide if it's a priority. If it is a priority, we can do a good study. As you know, they have begun to collect data because no one has done it for them.

I suggest that the effects of nasopharyngeal radium treatment are certainly an appropriate topic for study, and it is time to support the initial efforts of so treated, and it should be appropriate for us to do this scientifically.

Senator LIEBERMAN. Thank you, Doctor. I agree with you.

Let's go now to Mr. Farber, then we'll go to Ms. Kenneally and Mr. Garrity.

STATEMENT OF STEWART A. FARBER, SCIENCE ADVISER, SUBMARINE SURVIVORS GROUP, PAWTUCKET, RI

Mr. FARBER. I just want to raise one point in regard to Doctor Ducatman's comments before I get into my comments.

The treatments done to the Army Air Force personnel, starting around 1944, were done not just to pilots but to all flight crew members who had pressure changes as the bombers went up and down. So whole bomber crews were treated, in some cases in their entirety, not just the people who had symptoms. It varied from base to base, how they did their treatments, as documented in the open literature.

Senator LIEBERMAN. What's your estimate of what the numbers are here? Let's start with the military.

Mr. FARBER. In terms of numbers, we don't have firm numbers, of course——

Senator LIEBERMAN. I understand.

Mr. FARBER [continuing]. But right now we think there was something like perhaps 25,000 treated in the Navy through the 1950s, and probably an equal number in the Army Air Force, peaking in 1944 to 1945 when it was first done, when it was well documented that there were 6,881 individuals irradiated in one initial test of the treatment alone, and then it was done after that through the 1940s until such time as the Army Air Force began to pressurize its planes, or the Air Force started using pressurized cabins, and that eliminated much of the problem.

But at the time of World War II, in 1944—I should remark, this is off to the side—this was a wartime emergency. One of three men coming back from bombing missions over Europe was being grounded and sent to the infirmary by otitis media. It was a serious problem to supporting the war effort. So at that point, at least, it was a wartime exigency.

Senator LIEBERMAN. Could you just define otitis media?

Mr. FARBER. Otitis media is just the general name for conditions of the middle ear that affect both aviators and submariners, who have pressure changes, and young children.

Otitis media is today a very common medical problem with young children. It is the most common operation—it is the cause of the most common operation in children in the United States today. The latest figures that were published a few months ago were that about 680,000 children a year are currently treated with tympanostomy tube insertions, which is a surgical procedure that has, since 1954, been the method of treating otitis media. They insert this tube into the eardrum. Back in the 1950s the treatment was radium; that was the treatment of choice.

So that gives you some idea of how common otitis media is in children today, and back then. Back then, medical care was less available, but probably no less than 100,000 children a year were treated with radium in the 1950s.

Senator LIEBERMAN. Ms. Kenneally, you were one of those who was treated when you were a child?

Ms. KENNEALLY. Yes.

Senator LIEBERMAN. Okay. I think you made an important point there, which is that the reason why the people in the Air Force were being treated is that they were in non-pressurized cabins.

Mr. FARBER. Right. That's a very important point. Once they went to pressurized cabins it faded as far as the Air Force was concerned.

Senator LIEBERMAN. Whereas, as Mr. Garrity will indicate, submariners were generally being treated because they participated in this training exercise?

Mr. FARBER. Right. There were indications that it was done for people who had problems.

It should also be borne in mind that the original name for otitis media was "aviator's ear." That was in the 1920s and 1930s in England. That's what they called it, barotrauma or aviator's ear, because that's when the initial problem of this inability to equalize pressure presented itself.

Senator LIEBERMAN. Okay. Why don't you go ahead with your testimony?

Before you do, let me ask if you or Doctor Ducatman can answer this question which, for those who may be listening or who may be in the room, may be on their minds.

Sadly, almost everyone knows somebody who has had cancer who has been forced to undergo radiation treatment. A question that might occur is, what's the difference? In other words, this was a radium treatment; cancer patients are receiving radiation treatment. Would you answer that, either one of you, here at the outset for the record?

Doctor?

Dr. DUCATMAN. There are several differences. One is the dose. I am not an expert on the different doses used by radiation oncologists.

Another is the cause, the risk-benefit ratio.

Senator LIEBERMAN. What is the difference in the dose? Can either of you answer that?

Mr. FARBER. I have some information about that.

In the radium case, in the typical course of four treatments, this particular commercial irradiator delivered a dose on contact of about—by my calculations—2,000 Rem on contact.

Senator LIEBERMAN. And the Rem is——

Mr. FARBER. It's the unit of energy deposited in tissue, considering its biological effect.

Senator LIEBERMAN. That's 2,000 Rem on contact?

Mr. FARBER. On contact, with a depth distribution that varied inversely with distance. As you went away from the site of the irradiator, the dose went down. So a certain volume of tissue received declining dose with distance.

Senator LIEBERMAN. Right.

Mr. FARBER. The thyroid was actually quite remote from this in terms of the distance. We have to bear in mind that the thyroid did not get the major dose, the direct radiation dose in this treatment. The thyroid is 10 to 11 centimeters away. However, the immediate tissue got hundreds of Rem, and the contact dose was thousands of Rem for the typical course of four treatments.

In cancer therapy the typical doses are perhaps 4,000 Rem up to kill a healthy cell.

Senator LIEBERMAN. It's much higher, then?

Mr. FARBER. Approximately double, but it's of the same order of magnitude. But in the cancer case, you are facing a thing where the cancer is a potentially life-threatening situation.

Senator LIEBERMAN. Right.

Mr. FARBER. The risk-benefit equation is that, on average, the person benefits greatly from radiation therapy. As we know, radiation therapy has saved countless thousands of lives.

Senator LIEBERMAN. Right.

Mr. FARBER. Therefore—well, one of the points I was going to make is that we should not be condemning radiation therapy or diagnostic tests where indicated and properly performed. I think the public would be very ill advised to misinterpret what's going on today, or to be afraid of proper diagnosis and treatment. I'll get into that.

Senator LIEBERMAN. Yes. That's what I wanted to bring out here at the outset.

Doctor, do you want to add anything to that?

Dr. DUCATMAN. Well, the issue is risk-benefit ratio. If you're being treated for cancer, you have a wonderful reason to undergo the risks associated with radium treatment.

Senator LIEBERMAN. Right. Okay.

Go ahead, Stewart.

Mr. FARBER. My name is Stewart Farber. I was trained as a public health and environmental scientist, having received a masters degree in public health in the early 1970s from the University of Massachusetts School of Public Health. I earlier studied chemistry and worked for a few years as an R&D chemist before going back to study public health sciences.

I also have completed graduate course work in biochemistry and genetics and biostatistics at the University of Vermont College of Medicine.

Over the past 20 years my professional experience has focused on radiation risk assessment and improving radiation monitoring programs around fixed nuclear facilities. I have worked as a staff scientist and a manager for a number of nuclear power plants, as an environmental engineer and an assistant lab manager, senior radiological engineer, nuclear information manager, and operational support manager. For the other half of my career I have been a private scientist, doing consulting work for a variety of clients and health departments, and for the last six months with the Submarine Survivors Group as a science advisor, trying to help them advance the effort in terms of prompting the proper follow-up, in my opinion, of what is a significant public health issue.

As I said, Jim Garrity and I have been working together over the last six months, since we first met in late February or early March, and I was aware from the beginning of having heard about this treatment, and researched it—the level of exposure, the likely health risk to each exposed individual, and the collective dose and risk—because the size of the irradiated military and civilian cohort basically dwarfed all radiation exposure issues which have come to light since the DOE biomedical experiments issue has basically presented itself.

Senator LIEBERMAN. Let me just ask you to stop a moment and repeat that. Your judgment is that the potential impact of this form of treatment is greater than any of the others that have come to light?

Mr. FARBER. Yes, without doubt.

Senator LIEBERMAN. Just define in what terms you mean that. Is it numbers exposed?

Mr. FARBER. No, it's a combination of numbers exposed times the individual dose delivered to each person, and as a consequence of this treatment and based on what we know today and what is in the medical literature as excess risk related to this treatment—I'm not doing any extrapolations; I am simply, in later discussion, quoting what does the National Academy of Sciences' BEIR–V Report have to say about the excess risk of nasopharyngeal radium exposure as it was delivered in this country.

Based on those risk factors, this is, in its entirety when you look at the overall population exposed, far more significant in terms of overall radiation health effects than anything else that has come to light. Nothing comes close.

Senator LIEBERMAN. Then some of the military personnel, for instance, who were allegedly exposed to radiation as part of the experimentation to determine how best to deal with the potential for atomic war—more than that?

Mr. FARBER. Well, yes. The dose and the risk, as best we understand what doses those individuals received, the dose in this procedure and the risk from it, which is the important thing—what is the known risk relationship?—is far greater in the case of radium than any of those, either based on population, the total population, and the risk per individual.

Senator LIEBERMAN. Okay. Go ahead.

Mr. FARBER. As you know, an advisory committee was formed early this year, and a number of Federal agencies were directed to follow up, per Executive Order 12891, on the records to identify any individuals who have been subjects for human radiation experiments. As of early August, this project had 187 people at work and $3.7 million had been spent on that effort, with a completion cost estimated in the press at $24 million. I mention that because the activities of that group have not turned up any population that has the scale and the potential impact on health of the radium population. I just want to point out that thousands of people have come forward with their interest in this matter and registered with us, wanting proper health screening and evaluation, and this has raised a very important public health issue.

To go back to the evolution of this issue, in 1980 I became aware of the existence of this treatment because two of my co-workers came to me, as a radiation specialist, and described what they had been through in separate circumstances, neither of which involved military exposure. One had received it as a test engineer for Electric Boat; he SCUBA dived and had problems equalizing pressure, and his supervisor said, "Oh, we have a treatment we've been using for years; go see Dr. Henry Haines," who was a private physician at that point, and he was treated.

Henry Haines, as it turns out when I researched this, as a young Navy Captain developed this technique in 1944–45 for the Navy Medical Research Lab, and basically did the initial experiments—which I'll describe later—that were the source of radium being chosen as the method of choice for treating submariners.

The second co-worker received radium treatments from Dr. Haines in the early 1950s as a young boy growing up in Groton, with ear problems, as many young children do. He was also treated, and neither of them had any health problems that they knew of at the time related to this, but they were curious, as radiation-involved individuals working within the nuclear industry, as to what might be the problems. I set out to do a literature search.

I found basic information readily available in the open literature. I found that Dr. Haines at the time had done an experiment, that he reported in a medical journal in 1946 that discussed the nature of the irradiators, which are described on your blow-up there, and there was a common commercial irradiator. It involved radium sealed in a capsule in equilibrium with its daughter products. It was not by-product material. It was not supplied by DOE. It was natural radioactivity, and it was commercially available in large quantities.

Senator LIEBERMAN. This is a blow-up of an ad from a medical journal——

Mr. FARBER. Right.

Senator LIEBERMAN [continuing]. Advertising this treatment to doctors from a company called Radium Chemical Company, located in New York?

Mr. FARBER. Right. They were the primary manufacturer of this device, although another company made a similar unit.

This one company sold some 3,000 of those units from 1943—as they say in the ad, from 1943 to 1946, if I can read that—"more than 600 of these radium applicators are now used by clinics and specialists in the U.S."

Senator LIEBERMAN. Right.

Mr. FARBER. And they go on to describe all the wonderful things it can be used for: obstruction of Eustachian tubes; otitis in air and submarine personnel; cough secondary to nasopharyngitis—basically, smoker's cough, they were saying that it worked to solve that problem; obstinate cases of chronic otitis media; and recurring attacks of acute otitis media, various fine points about what kind of ear problems you're having with this middle ear fluid buildup.

Okay. In any case, I started looking into this and I realized that I'm spending my professional career worrying about picoCuries, which is a millionth of a millionth of a curie, and milliRem and microRem, which are millionths and thousandths of a Rem, and this treatment delivered thousands of Rem to the nasopharynx of what was obviously thousands of healthy young people. What it worked out to, it was the equivalent of taking one gram of pure radium, a Curie, and sticking it up your nose for approximately two minutes, on average. Some people had many more treatments because the lymphoid tissue would grow back, and therefore they would have recurrent treatments. Some people had as many as 20 and 30 treatments. Then they would have had doses to the nasopharynx of 10,000 Rem and higher.

But again, this was all in the open literature. The treatment was then decided, after the initial experiment by Dr. Haines, to be the treatment of choice, and it was used from that point forward. I was aware that there were at least 10,000 submariners treated, from initial looks at the numbers of submariners who trained during the 1950s. That was based on 30 percent of men who typically could not equalize pressure, and the numbers of men who went through.

But the key thing was, what was the risk? I found a paper published in a BRH—Bureau of Rad Health—publication in 1980 which was, and is today, the only study that has ever been done on nasal irradiation in this country as it was done, that has any real merit. This was a paper by Dale Sandler that was first published as a preprint or an abstract in 1980 by the Bureau of Radiological Health. I'm just going to read the summary of what it said.

Senator LIEBERMAN. Do you know at all what engendered that study?

Mr. FARBER. I'm not the one to speak to that point. Dale Sandler, who is here today, could probably tell you. It was basically a Ph.D. thesis, a research topic, and I don't know the whole history of it.

Do you want her to come up?

Senator LIEBERMAN. Sure. Come on up just for a moment.

Dr. SANDLER. I am Dale Sandler. I'm an epidemiologist at the National Institutes of Health, Environmental Health Sciences in North Carolina. I did this study as my doctoral dissertation while I was at Johns Hopkins.

The reason I did this study was that at the time there had been a number of studies of other head and neck radiation treatments, where children were exposed for a variety of conditions and were showing up 10 or 20 years later with increases in thyroid cancer. There was a lot of publicity about this and much concern. The children were treated for ringworm of the scalp, for acne, for enlarged thymus glands, and maybe a dozen cohorts had been studied. Nobody had really looked at this treatment.

When I was at Johns Hopkins, the treatment had actually been pioneered there for use in civilian populations of children for prevention of deafness in school kids. One of my thesis advisers was aware that there was a cohort of children who were treated in western Maryland, Washington County, and the records mysteriously appeared one day during a move by the health department. This seemed like a really interesting opportunity to study a different kind of treatment with a lower dose to the thyroid.

Senator LIEBERMAN. Thanks. I'm delighted that you're here. I appreciated it.

Mr. FARBER. The study basically involved 2,925 children who had attended a hearing loss clinic, and this was the treatment of choice; 904 received radium treatments from 1943 through 1965, and they were able to trace 90 percent of them. They found—I'm just going to read exactly what the results were in this first report:

> There was an overall statistically significant increase in benign and malignant tumors of the head and neck among the irradiated patients compared to the nonirradiated. Although there were no thyroid tumors, there was a statistically significant increase in other thyroid diseases (a combination of hyperplasia, nodular goiter, and thyrotoxicosis) and of thyrotoxicosis alone. Of the four malignant tumors.

And I note in my testimony that these were deaths, not cases—

> Of the head and neck, three were brain tumors; there were no malignant tumors of the head and neck in the nonirradiated group. Although the radium treatment was intended to prevent hearing loss, more hearing loss was subsequently found in the irradiated than in the nonirradiated group.

The impact of this, as stated by the original author:

> The findings of the study will be part of the rationale used in the development of Agency decisions regarding risks. Study participants have been advised to have

their hearing examined, and the irradiated patients have been advised to have their thyroid glands examined.

In 1977, Johns Hopkins Hospital sent out a medical advisory to the medical profession and to the general public, advising them that if they had this treatment, they should get back to an ENT specialist for an exam and have a full exam, and if there's an indication of thyroid problem, see a thyroid specialist. That recommendation reached a rather limited audience, and was not acted upon by anyone in Government or in the military, and in 1992, when my letter was published——

Senator LIEBERMAN. That was 1977.

Mr. FARBER. Seventy-seven, January 1977. They were obviously aware at Johns Hopkins, as the original developers of this treatment, there were likely to be some outcomes.

Senator LIEBERMAN. Right.

Mr. FARBER. And they were, I think, beginning to address that concern by perhaps pushing to do a study, a small study of radium or radiation that Dale Sandler, Dr. Sandler was involved in. And they took some actions to at least give some notice at that time.

Senator LIEBERMAN. Right.

Mr. FARBER. And the full unpublished paper of Dr. Sandler's was presented at a later symposium in 1980 that was run by the Bureau of Rad Health. And I'm not going to quote from it, but it's in the paper, in my testimony.

Senator LIEBERMAN. Your testimony will be printed in full in the record.

Mr. FARBER. But it basically makes the point that there were significant excesses of benign and malignant head and neck tumors that were statistically significant, even brain cancer alone, I want to quote, "As can be seen from Table 5, there appears to be an excess risk of mortality from brain cancer in the exposed group which is significant with a p value of 0.01." Again, we have the dry language of epidemiology at work here. But a p value of .01 means there's one chance in a hundred that number of brain cancers could occur by chance. That is generally assumed in many studies to be, to show some level of significance that is given some credence.

Senator LIEBERMAN. Pretty high. Right.

Mr. FARBER. They also said in the study, because of the impacts of it, because of its proximity to the radium applicator, the pituitary gland was exposed to the highest dosage of radiation, receiving 51 to 207 Rads for a three treatment course. It was felt there might be hormonal changes associated with such an exposure.

They found in that Sandler study a 8.6 fold higher rate of thyrotoxicosis, which is enlarged thyroid, which they hypothesize was related to pituitary irradiation and imbalance of hormonal control through thyroid stimulating hormone of the thyroid gland. The thyroid enlarges and causes various health effects. And while it's not malignant, it could be a very severe interruption of normal bodily function.

That point alone is what makes this study so fascinating from a medical/scientific point of view. There's likely to be pituitary involvement that has other health effects besides thyrotoxicosis. And when the pituitary is upset, you affect things like, well, female sex hormones. The ovaries' production of FSH and LH are related to pituitary control, and Fran Kenneally will testify about the possible effect of this treatment.

Okay. I'm going to leave the Sandler study, but I think you'll see in my testimony it went through an evolution in the final publication, the Journal of the National Cancer Institute, in 1982, the abstract was a little less direct in its statement, that I think confused Navy investigators later who reviewed this. The abstract on the paper says that: "18 to 35 years after admission to a clinic for prevention of deafness, no increased overall cancer risk could be detected among 904 persons who had been treated with nasopharyngeal radium irradiation compared with the risk among the control group" basically.

I think with that lead, people who looked at it quickly missed the significance of this study. And you can debate why they changed the emphasis from earlier preprints of the paper. I'm not going to comment on that except to say, that's how the final publication occurred in the somewhat reduced length paper in the Journal of the National Cancer Institute.

Anyway, so in 1981, I tried to get the study going on this. I walked the halls of Harvard School of Public Health. I met with epidemiologists. Nobody wanted to look at this. Nobody said they had money. Nobody said they would take the time. Basically it went nowhere.

I arranged a meeting with Dr. Haines in 1982 with one researcher from MIT who had been involved with the radium dial painter studies. Dr. Haines was not honest in his recollections of the status of his records at that time. He basically told the investigator all his medical records had been destroyed, and therefore the study could not go anywhere. He also said all the medical records by the Navy had been burned by a fire in St. Louis, and nothing was available. That, as we found out subsequently, was not the case.

For a number of reasons, however, this is a potentially significant study. As Dr. Ducatman and I discussed in our meetings in 1989, when this thing slid in 1989, there were a lot of good reasons to do a study. It looks like there is, based on the limited literature that exists, a suggestion of a significant excess of benign and malignant cancers of the head and neck, which is the better way of looking at the effect on this, not just one site, but the overall effect on the head.

Because the exact site of a cancer may be determined by various factors that are difficult to ascertain. You're better off looking at the overall cancers of the head and neck in exposed versus non-exposed individuals in a population of only 900 individuals.

However, the point is, if you can't do an epidemiological study on 5,000 subjects, which was the conservative size of the original cohort Dr. Ducatman and I had estimated, and exposed to these kinds of doses, with localized dosimetry that's reconstructible, if you can't do a decent epidemiological study on this cohort, then there is no cohort that exists in the world today on which you can do a decent epidemiological study of the effects of radiation on health. You're wasting your time talking about doing down-winder studies from Hanford or people in the environs around Savannah

River. Because there you're talking trivial doses by comparison in any fallout population——

Senator LIEBERMAN. So what you're saying here is that this is feasible, that such a study is——

Mr. FARBER. It's definitely feasible, yes. We have a large—we know now we have not 5,000 individuals or 10,000. We've got 50,000 vets. We've got hundreds of thousands of children that have received a focused, intense irradiation to the base of the brain. If we can't see the health effects of this in a decent study, with good sensitivity and good statistics, there is no study that can be done that means anything, that's my opinion.

Senator LIEBERMAN. I'm going to have to ask you to begin to wind up. But let me ask you, because I presume that it was Secretary O'Leary's public statements regarding the other Federal Government experimentation, or treatment, experimentation certainly in that case, with radiation, that stimulated you to raise these questions again publicly——

Mr. FARBER. Oh, absolutely.

Senator LIEBERMAN [continuing]. This year. Okay.

Mr. FARBER. I saw that this study, based on the climate of early January or late December, if this study was ever going to be done, this was the time to basically force the issue.

Senator LIEBERMAN. Right.

Mr. FARBER. So I set out on a personal campaign to bring it to the attention of you and other Senators and Congressmen, to various parties that I felt would have a stake in this, and here we are.

Senator LIEBERMAN. Clearly, part of my interest, as I suppose is obvious, is that there are so many submariners around.

Mr. FARBER. Yes.

Senator LIEBERMAN. Not only because the base is there in New London, but because a lot of the folks continue to live there. And Dr. Haines was there, treating a substantial civilian population as well.

Mr. FARBER. Yes. I cite in my written testimony the warnings in 1949 at a medical conference about nasopharyngeal radium irradiation. A Dr. Isadore Lampe cautioned that doses of this magnitude should not be used except to treat cancer, or malignancy, as he termed it. And that's the basic point. You do this where the risk benefit justifies it. But children with various runny nose problems and recreational scuba divers don't need radium up their nose.

In my case, Jim Garrity and I got together in late February, March. This thing has grown exponentially. In my review of the literature, it's clear the initial use of radium by the Navy in Dr. Haines' experiments were and do meet the definition of a human radiation experiment.

We put out a press release on 7/1 that's described in my testimony that shows without doubt that Dr. Haines in his statements makes it clear this was an experiment. The 732 submariners treated were described as follows: "Merely another clinical study would not meet the need."

These are Dr. Haines' words.

> In view of the fact that we had a rich source of material, and since every condition necessary for rigid experimental control was available, we felt it possible to meet rigorous research criteria, and thus to provide a fairly definitive study on the

causes, effects, prediction and treatment of the disorder. The present report describes otitis media as it appears in submariners, and recounts the experiments by which we attempted to understand it and mitigate its effects.

So again, that makes the point, the initial use, at least, was an experiment, and that's without doubt.

Senator LIEBERMAN. Okay. Again, that's an important point. You're saying that from Dr. Haines' statement?

Mr. FARBER. That's his own words in his medical report that I cited.

Senator LIEBERMAN. What was happening here was that he was experimenting with this treatment on the submariners who were part of the——

Mr. FARBER. Right. He actually put together an experiment where he looked at things like chewing gum, did that help with pressure equalization, listening to music, various threats of cancelling leave, did that help people go through pressure testing more successfully. Various odd and sundry psychological treatments of that sort, as well as neosynephrine drops and other treatments. And they decided radium was the treatment of choice.

Senator LIEBERMAN. So you would say, I presume, I don't mean to put words in your mouth, but, obviously the Government has some kind of responsibility, and I think so, regarding the treatment it provides to people in service, and the effects of that treatment. But, I presume that one thing you're suggesting here from the statement from Dr. Haines is that if, in fact, this was experimentation, then the level of governmental responsibility is even greater.

Mr. FARBER. Absolutely. And I think that makes that point absolutely clear. It was an experiment by the words of the initial investigators themselves. And this was a Navy Captain, published in the open medical literature in 1946.

As the last point, we pointed out the doses and the risks of this radium procedure, based on the National Academy of Sciences risk factors published in the BEIR–V report, which is the latest summary statement of the known effects of ionizing radiation on health. The BEIR series is an acronym, BEIR, biological effects of ionizing radiation.

In that study, they cite only one study of radium effects of health, nasopharyngeal radium. It's the Sandler 1982 study published in the Journal of the National Cancer Institute. And they point out there were three brain cancers observed, where only 0.57 were expected, and that results in a net excess of 2.43 cases among 902 children.

While it sounds like a "slight increase" and many people have termed it thus, that slight increase, when you look at it in terms of the population exposed, predicts, and if you take a population of 80,000 individuals irradiated, a total brain cancer excess of about 260 cases in that exposed population followed for 24 years. Those aren't my numbers, they're the National Academy of Sciences'.

Senator LIEBERMAN. Right.

Mr. FARBER. That compares them to the entire life span study cohort of the Nagasaki/Hiroshima case of 250 cancer deaths from all sites. So just on brain cancer alone, the radium treatment exceeds the predicted cancer excess of Hiroshima and Nagasaki.

Again, that's not an extrapolation. That's a simple statement of what the current literature and the current report from the NAS documents.

Senator LIEBERMAN. Let me clarify, because that's a very powerful statement. Just let me see if I understand. What you're saying is, based on the studies that have been done, and, understanding that there's a limited literature with regard to the effects of the radium treatment that were focused on, but nonetheless, with regard to that, that the excess risk of cancer, brain cancer——

Mr. FARBER. Alone. Brain cancer alone.

Senator LIEBERMAN [continuing]. Alone, for those that had the radium treatment, nasal radium treatment, is greater than the excess risk of brain——

Mr. FARBER. Of cancer of all sites, cancer, leukemia——

Senator LIEBERMAN. Cancer of all kinds.

Mr. FARBER. Every site that was observed in Hiroshima/Nagasaki.

Senator LIEBERMAN. In people who were in Hiroshima and Nagasaki?

Mr. FARBER. At the point of the blast, at the site of the bombing of Hiroshima and Nagasaki.

Senator LIEBERMAN. Okay. That's a very powerful and troubling statement.

Doctor, do you want to add anything?

Dr. DUCATMAN. Yes. I'd like to just add a small qualification to that.

Senator LIEBERMAN. Go ahead.

Dr. DUCATMAN. In epidemiology, for thought experiments, it's sometimes okay to take a very small study and project it into large numbers. But that is a thought experiment. In fact, we don't know that that is an appropriate thing to do.

If it turns out that that is the case, that we could do that, then we would have all these excess cancers. But we don't know that. That's the question. That's why we have to do a study.

Senator LIEBERMAN. And that is because we haven't studied those who received the radium treatment of the nose enough to reach the conclusion?

Dr. DUCATMAN. That's right. You can't——

Senator LIEBERMAN. Whereas, the statistics with regard to those who were at the site of explosion in Hiroshima and Nagasaki are, the studies are ample.

Dr. DUCATMAN. Well, there are some questions about that. But let's leave that separate issue aside.

Senator LIEBERMAN. Okay.

Dr. DUCATMAN. Let's go back to the radium treatment, and just say that yes, if you took that one study and projected it, what Mr. Farber said would be quite alarming. And in fact, that's the reason why it's worthwhile to do a study.

Senator LIEBERMAN. And that's the reason why you——

Dr. DUCATMAN. But it's a question, not an answer.

Senator LIEBERMAN. Okay. That's the reason.

Mr. FARBER. It's the best information we have at the moment.

Senator LIEBERMAN. Right. And that study again is Dr. Sandler's study?

Mr. FARBER. Sandler 1982 study that I cite. I should also point out that the risk estimate that the BEIR report cited for her study is in line with many other studies of brain cancer risk in terms of how many cases of brain cancer you see per person year Rem. It's not like it's some outlier of risk. It's in line and it falls within a range of values that is not likely to be anomalous. And I think that's an important point.

I'll just close on one point, that while this was an unusual treatment, it does not reflect on current practice, and the public should not be terrified of getting properly indicated, properly performed medical evaluation now. It also is important to realize, it took a carefully designed epidemiological study of the Hiroshima and Nagasaki survivors to see a 5 percent increase in cancer mortality and a 1 percent increase in total mortality among those survivors. The bombings caused those effects.

We're going to have to do a damned good study of this population to see the effects in a methodical, scientific way. It's going to have to be designed right, and it's going to have to be executed right. Otherwise, you're wasting your time and your money.

And lastly, I just want to close with a bit of philosophy that's kept me motivated on this whole issue from the start. It's a quote by Erwin Schrodinger, of Schrodinger's Equation, Etc.:

> It seems plain and self evident, yet it needs to be said, the isolated knowledge obtained by a group of specialists in a narrow field has in itself no value whatsoever, but only in its synthesis with all the rest of knowledge, and only in so much as it really contributes in this synthesis towards answering the demand; Who are we?

Senator LIEBERMAN. Well said. Thank you. I appreciate all you've done. And we appreciate your testimony this morning.

So I conclude from listening to both of you that at a minimum, as you've said, Doctor, there's enough here to be concerned about to ask more questions, and for those who receive these treatments, not to panic, but at least to go to a doctor and indicate to their doctor that they've had the treatments, and they should be watched for any potential effects.

Dr. DUCATMAN. Medical surveillance for those so treated would be very prudent advice.

Senator LIEBERMAN. Right.

Okay, now we move to people who received the treatments and who have gone through in their own experience a lot of pain and suffering that may well be related to them. Fran, you pronounce your last name Kenneally?

Ms. KENNEALLY. Yes.

Senator LIEBERMAN. Okay, not like the Congresswoman Kenneally. Okay, Ms. Kenneally, we welcome you here, and we look forward to your testimony now.

STATEMENT OF FRANCES KENNEALLY, WATERFORD, CT

Ms. KENNEALLY. Thank you.

Good morning. My name is Fran Kenneally. I was born and raised in Waterford, Connecticut.

When I was between the ages of 6 and 8 years old, my parents brought me to an ear, nose and throat specialist, Dr. Henry Haines. He diagnosed that I had adenoid trouble. At that time, Dr. Haines was using the radium rods to treat the adenoids. I went to his office, and he put these rods up my nose.

After about a year and a half of these treatments, he finally removed the adenoid, along with my tonsils. After this operation, I started getting nosebleeds. I was taken to the hospital on several occasions and had my nose packed, cauterized, and then I would have to go to Dr. Haines' office, and he would do the same thing.

I remember that I was just really, really frightened going there, because I knew that I was going to have this treatment done. I had one solace, he had plenty of comic books, and he let us read comic books. But I know I blocked alot of things out, being so frightened.

Sometimes he would have us laying down, sometimes sitting up. But all I remember is I just despised the treatment.

When I was 14 years old, I began having a lot of female problems, consisting of irregular and painful menses, and at the same time, I was having really excruciating headaches. So I was brought first to a gynecologist, and he did some tests, and he explained that I had an infantile ovary, and that I would more than likely always have female problems.

So the headaches were so intense that I would have to go to bed. And my parents thought, well, they'd better bring me to a neurosurgeon. So he did some testing, and for example, there were EEGs, evoke response, sinus x-rays. He sent me to an ophthalmologist. He also sent me to a dentist, and the dentist said that it might be my teeth, so he pulled two on each side of my front teeth. And come to find out, it wasn't my teeth at all. I still had the headaches.

For some reason, they just subsided. I didn't know why. During the time that I had them, they gave me painkillers. But the doctor said that maybe they went along with the gynecological problem.

In 1966, I was married, and I was still having a lot of female problems. I became pregnant with my first child, and I miscarried after a six-week pregnancy. In December of 1967, my son was born. He was born brain damaged. From the time I was 23 to 35, I had five more miscarriages. And at that time, I never knew that I was pregnant, because I never had the menses. They were always late. And there were times also that I thought I was pregnant, because I had lactation from my breasts all the time.

Well, my gynecologist referred me to a Dr. Burton Caldwell in New Haven, Connecticut. He's an endocrinologist. And he did a test, concentrating on the prolactin level in my bloodstream. Now, a prolactin level in a nursing mother is usually at a level of 25. At that time, mine was over 300.

He then began more testing. He did a CAT scan of my head. When they initially started the tests, they found out that I was allergic to the dye. And they only did part of the test. So they did find a growth in the brain, but they really couldn't define any of its properties or were able to tell, you know, what it was.

So he tried a new drug that came on the market called Bromocriptine to try and shrink it. Well, I went into anaphylactic shock, because I was allergic to that. And they admitted me into the hospital. And my gynecologist, with Dr. Caldwell together, were going to administer this pill to me a little bit at a time to see if I could take it. Well, as fate would have it, I couldn't take it.

And they sent me to Mass General. I went to Mass General Hospital. They had a new machine there called an MRI. They discovered that I did have a pituitary gland tumor. If I had chosen to have an operation to remove it, they would have to leave a portion because of where it was located. And they were afraid that it would increase in size, that portion that they left, and that the portion that they removed, it would probably grow back.

So they told me, also there would only be like a 40 percent chance that everything would be fine after the operation. Well, having a handicapped child that was my main interest, I chose to search for other options. So I left Mass General, and I learned of a clinic at Yale, New Haven. And they experimented with drugs that were legal in Europe, but not in the United States. So I decided I would give that a try. So I was monitored daily.

I could not take the drug. They said if I continued another week, I would have irreparable damage to my kidneys and my liver.

So the only thing left was the radiation treatment. So I decided to opt for this. I had 25 cobalt treatments at Uncas on the Thames Hospital. The doctors at this facility told me that it was very possible that I could have this tumor since I was 14 years old, that——

Senator LIEBERMAN. And again, you received the radium treatments in your nose at what age?

Ms. KENNEALLY. Between 6 and 8 years old, for two years.

Senator LIEBERMAN. Thank you.

Ms. KENNEALLY. Also during that time, the pituitary gland would not work correctly with the tumor where it was located. It would admit lots of hormones that weren't needed. And I would faint from too much adrenaline. My heart would race all the time because of my thyroid not working properly.

And just a little bit of background, I'm a single parent of a mentally handicapped child. And he had problems dealing with this, like I would faint. He would step over me rather than deal with it, because, you know, this wasn't happening. So after a short time, I had a friend of mine, Jeanne Brennan, move in with me. And she's still with us now. And she still stays with us.

Throughout all my illnesses, I continued to work. After radiation treatments, it was found out through the MRI results that the pituitary gland and the thyroid was burned out. So now I have to have synthetic hormones for the rest of my life. I produce no estrogen. I have osteoporosis.

Senator LIEBERMAN. This is because the pituitary gland and the thyroid were burned out by the treatment you received?

Ms. KENNEALLY. By the treatment.

Senator LIEBERMAN. By the later treatment?

Ms. KENNEALLY. By the later treatment.

I have to have bone scans every 6 to 8 months, and my bones are beginning to weaken steadily. In fact, last year I had pneumonia and I broke a back rib just coughing. The doctors are hesitant to treat me, because anything that they give me, even aspirin, I end up with reactions to that they can't define why.

Well, late last year I read an article in my hometown paper about Jim Garrity, the problems he had encountered having nasopharyngeal radium irradiation treatment. This caused me to remember my own treatments, and I contacted my doctor, Dr. Caldwell, to ask him if maybe this treatment could have something to do with my tumor. He said that there wasn't enough study done or any proof to say yes, but to give Jim a call and find out more about it.

The past few years, my health has really been declining. I just finished having a series of 12 compression casts on my leg. I had an infection, none of the doctors knew what it was. I was again sent to Yale. They put these compression casts on as experiment, because I could not take any of the drug treatments that they would normally try. I've had a TIA, a mini-stroke, that they don't know what it came from. This happened on my job.

My general practitioner, Dr. Chris Morren, said that it was an observation, not a proof, but in the back of a normal mouth, you see normal pink tissue. But any patients that have had the radium rod treatments have a web of white scar tissue in the shape of an O in the back of their throat. It was quoted by Dr. Morren in an article, he quotes, he said "Until recently it was just sort of a phenomenon. But now we should actually take this into account in medical histories."

Not one member of my family has had any sicknesses I've had. My maternal grandmother lived to be 98 years old. All the doctors I have been to are totally baffled with me. And I feel like right at this point that they all have been passing me around to say, "Look at this one." Some doctors really also have been truly frightened and they hesitate to treat me because of my medical history. I was just told not to work anymore and am now out of work waiting for disability.

And in closing, I really in my heart feel that the radium rod treatment I had as a child contributed to this past and my present health problems. And I would just like to thank you for letting me speak.

Senator LIEBERMAN. Ms. Kenneally, thank you very much for your willingness to come forward and speak openly about this. Obviously, we hope that this whole process, including your testimony, will lead people who may hear about it to remember that they had this treatment and again not to panic, but to let their doctors know so that they can be monitored for conditions like the ones that you've unfortunately been forced to undergo.

Ms. KENNEALLY. Well, that was one of the main reasons that I came here, is that maybe they wouldn't have to go through all this, all the years. It's been over 40 years since I was 8 years old and had these treatments and had the adenoids removed. And it took this long to find out that maybe that's why.

Senator LIEBERMAN. Maybe that's why. It's probably hard to remember 40 years ago, I don't know whether you've had a chance to speak to your parents, whether they're still alive, but whether there was any warning given prior to the treatments by Dr. Haines that there might be problems associated with them, or whether you and your parents had any sense that these were unusual treatment?

Ms. KENNEALLY. Not that I know of. Because I don't think my parents would have let me go through it if there was any kind of danger. But both of my parents are deceased.

Senator LIEBERMAN. Right. Thanks again. Thanks very much.

Jim Garrity is our final witness on this panel, the President of the Submarine Survivors Group. He's been a real leader, I would say hero, in this effort. I have tremendous admiration for your service to our country, and your service after, including in the last year or so on this case. So it's good to have you here, Jim, and I appreciate your testimony.

STATEMENT OF JAMES J. GARRITY, JR., PRESIDENT, SUBMARINE SURVIVORS GROUP

Mr. GARRITY. Thank you, Senator.

My name is Jim Garrity, and I'm testifying today not only for myself, but for the tens of thousands of military and civilian individuals who have contacted the Submarine Survivors Group Hotline.

My personal experience with radium irradiation began in 1966, as a young man of 18, attending Submarine School down in New London, Connecticut. And all the volunteers in the first two weeks were required to go through the escape tank that they had down there, it's a 100 foot tall column of water, 25 feet cylindrical. And we had to go on a free ascent from the bottom to the top, to simulate an escape from a disabled submarine.

Senator LIEBERMAN. Why don't you describe it in a little more detail, because this is very relevant.

Mr. GARRITY. What happened in the tank, you were pressurized, you went through the dry tank first. And the dry tank simulated the pressure down to the X number of feet that they would bring you down. And at that point, they would stop this on several occasions, because the trainees could not equalize the pressure, and they would have to bring the pressure back up so that they could let these individuals out.

Senator LIEBERMAN. When you say couldn't equalize the pressure, you mean within their own ears.

Mr. GARRITY. Within their own ears, right. It was part of us learning how to escape. And many times, going up the tank, the dry tank proved a lot of things for a lot of people, you know, that they couldn't equalize the pressure in their ears. I made it through the dry tank and went to the wet tank. And when I entered to the wet tank, I would go right to the surface. And when I reached the surface, both my eardrums were bleeding, were broken. And I just couldn't equalize the pressure.

Senator LIEBERMAN. Did you have pain in your head?

Mr. GARRITY. Tremendous pain. It was like my head was in a vice. It was, I'll never forget that feeling as long as I live.

Senator LIEBERMAN. Did trainees who couldn't survive the test, as it were, not gain admission to the rest of the program? Or was it not a disqualifier?

Mr. GARRITY. Well, at that point, in 1966, they would get the treatment. And if they could equalize the pressure in an X period of time down the road, they would qualify in the tank.

Senator LIEBERMAN. After the radium treatment?

Mr. GARRITY. That's right. You know, one of the things that I have to point out here is that I'm proud that I was a submariner. And I'm proud that I served the United States Navy. But it's now that we're understanding what went on back then. And I—it's something that we can do something about.

When I got to the surface of the tank, a Navy corpsman realized how bad my ears were bleeding, and I was sent to the infirmary, or the medical research lab that was on the base for the treatments for the next two weeks. Upon completion of these radium treatments, I was required to requalify in the escape tank, and did so without any problems at all.

Senator LIEBERMAN. Well, presumably that was a result of the effect of the treatment on your own——

Mr. GARRITY. That's right. You know, submarine service is a very proud service. It's something to be proud of, and I am. And we didn't want to be washed out.

Senator LIEBERMAN. Right.

Mr. GARRITY. You know, we would do anything not to be washed out. We went through a grueling, grueling testing as far as schooling and physicals and everything. We didn't want to be washed out. We're a proud breed.

Senator LIEBERMAN. Right.

Mr. GARRITY. I went on to serve in the United States Submarine Service and was honorably discharged in 1973. My health problems began to appear about 10 years ago, when I would lose my voice for long periods of time. I developed a chronic runny nose, which would get worse when I ate. My teeth began to break off for no apparent reason.

And I went to a number of doctors, and they couldn't find anything organically wrong. And they kept saying to me that, you know, maybe it's in your head. And it's something that, you know, I have to point it out because I hear this time and time again on the phone. The doctors were saying that it was in their head. And they had me almost believing that it was in my head, there was something wrong. I resolved myself to the fact that I was going to be sick and I was going to feel this way my entire life.

At the beginning of 1994, I read an article in the Albuquerque Tribune, in which they cited the report that Stewart Farber and Alan Ducatman had published.

Senator LIEBERMAN. Where did you read it again?

Mr. GARRITY. In the Quincy Patriot Ledger. It was a reprint from the Albuquerque Tribune.

Senator LIEBERMAN. Right.

Mr. GARRITY. And it told in there of a number of neck cancers in that it was given to submariners. And I remembered those treatments.

Senator LIEBERMAN. You'd never made the link before between your health problems and the radium rod treatment?

Mr. GARRITY. Never made the link at all. Never once. Never once.

It was almost like my prayers were answered. We could now put something.

So what I did was, I sent, I had called the Patriot Ledger in Quincy where I live, and I asked them for more information. And they sent a reporter to my house. And they started to publish reports. That was the start of a series of articles that went across this country.

And it was almost immediately that I started to receive calls and letters from ex-military personnel and members of the general public who had received the nasal irradiation and experienced various adverse health effects which might be linked to radium treatments. As more articles were published and written and published, more calls and letters were received and a pattern started to emerge on these contacts.

It was not long before I was contacted by Stewart Farber, who had been involved in research of this issue. We had a chance to meet, and we started the Submarine Survivors Group. Since the start of our endeavor, we have used our own money and donated our own time to research and collect data from thousands of individuals who respond to the Submarine Survivors Group Hotline.

The calls pouring in tell my story and similar stories of brain cancers, thyroid cancers, and acoustic neuromas, and facial neuromas, and of various conditions likely linked to radium irradiation time and time again. This treatment had almost no boundaries in that it was given to both military and among the public, who are now suffering the after-effects.

Senator LIEBERMAN. Jim, can you just in general terms, really rough percentages, breakdown the calls you receive, how many are from the military and how many are civilian?

Mr. GARRITY. I have that information for you, Senator. To date, total calls and letters, 53,412. Of that, 23,749, which represents 44.5 percent, are veterans that are living. One thousand eight hundred and forty-three, which represents 3.4 percent, are veterans that are deceased, and their relatives are contacting us. Dependents of veterans treated by military physicians, 8,634, for a percentage of 16.2 percent. And the civilians that have contacted the hotline, 19,186, which represents 35.9 percent.

Senator LIEBERMAN. That's very helpful. Let me ask you, on a related question again, I don't know if you have these numbers specifically, of those who have called, what percentage have experienced health problems that they worry may be associated with the treatment, and what percentage are just calling to say, I remember I got this treatment, either in the military or as a child, and I'm worried about what the effect may be?

Mr. GARRITY. More than 75 percent of the people who call, they have some sort of health problems. The others are curious and they—they're not sure. They're really not sure. You know, they have the runny noses. They have the headaches. They have the teeth that are breaking off.

But out of that 53,000 plus, it's—everybody's concerned.

Senator LIEBERMAN. Sure.

Mr. GARRITY. And I brought today just a sampling of the letters that pour into our hotline and the contacts. It's a big problem.

I personally answer the hotline and read the letters received. Some days I feel so helpless because people who have contacted the Submarine Survivors Group need help in understanding. Stewart Farber and I are only two individuals who are working to make sense of this information. Some nights I work all night. And there are days I have to walk away from the phone and cry. The stories I'm hearing of death and disability in whole families is overwhelming.

After starting the Submarine Survivors Group Hotline, I had the last of my teeth extracted, and my dentist wanted me to have a physical. My physician found cancer in my nasopharynx, and this quest took on a whole new meaning. At this point, I could have quit and I could have buried my head in the sand. I didn't. I chose to keep it going, so that I could help other individuals going through this.

When people call me and tell me of their experiences, I urge them to get a complete physical and have their thyroid checked. On a number of occasions, and I can't put a figure on this, Senator, but on a number of occasions, people have called me back, and they have written me, thanking me, because we caught the cancer and we caught the problems early enough that they can be helped, and they can live a normal life.

You know, for other people it's not so easy. Their loved ones call or write that their father, their husband, or their uncle have died of brain cancer, suffered from thyroid disorders that they can't explain. I feel helpless but I try to explain what might have happened.

One of the first calls I got was from a lady in Quincy, Massachusetts, who stated that her husband had died. And he had treated her very badly over the last month or two of them being together. This lady was crying. And I got hold of this gentleman's Air Force medical records from her, and I tried to explain to her what might have happened, that he had simply lost his mind and he just didn't know what he was doing.

She cried to me and she said that I had given her her husband back. When I got through, I cried.

Gentlemen, we need help. Together we can make a difference. We can help many thousands of people who got this treatment by getting them to see their doctors, so that any problems can be detected early. We can also help explain some of the health conditions which affected people who have passed away, thereby increasing medical knowledge about the effects of radiation exposure on their health.

Now is not the time to hold back information. Now is the time for action. We have a chance to make a difference in so many peoples' lives. The Submarine Survivors Group is cooperating with the United States Veterans Administration, the Epidemiologists Department, and we will cooperate with any Federal or state agency that needs our help.

Thank you for this opportunity to testify.

Senator LIEBERMAN. Thank you, Jim. Thanks for everything you've done and for your testimony. And believe me, you are making a difference, and I'm going to stick with you until we see that as many people as possible, who received this treatment, know about the potential dangers and go to see their doctors, and that we get this study done, so that we can reach some conclusions, and hopefully that we get some treatment for the veterans, availability of treatment for the vets.

Let me ask you a final question. Describe, if you would, any contact that you've had or has been made with you from any of the Federal Government agencies about the information that the survivors group is gathering.

Mr. GARRITY. What we have done is the VA Epidemiologists Department called me and asked me if I could provide them with 24 names of individuals who were in the service, you know, 12 from the Submarine Service and 12 from the Air Force, Army Air Force or Air Force, period. And I contacted these veterans, I got their permission, I got signed releases. And I gave this over to the Veterans Administration, who are now researching the availability of getting their records.

And let me add this, too, that the service records that the veterans who have been calling me, I have a number of the service records already available to us. They're on a confidential basis, but I do have those records. And we will cooperate with anybody that wants our help.

Senator LIEBERMAN. Okay. That leads us to the next panel of Government witnesses. I want to thank all of you for what you've done to describe the problem, to bring it to public attention, and we look forward to continuing to work with you. God bless you, Jim and Fran, and we hope you're feeling better as time goes on. Thanks very much.

Ms. KENNEALLY. Thank you, Senator.

Mr. GARRITY. Thank you.

Senator LIEBERMAN. Now, we'll call the second panel, Dr. Susan Mather is the Assistant Chief Medical Director for Environmental Medicine and Public Health of the Department of Veterans Affairs. Dr. James Smith, Chief of Radiation Studies Branch, National Center for Environmental Health and Injury Control at the Centers for Disease Control, Department of Health and Human Services. Major General Robert A. Buethe, Jr., Acting Surgeon General of the Air Force, and Rear Admiral Harold M. Koenig, Deputy Surgeon General of the Navy.

We appreciate the presence of these witnesses from the Federal Government who have heard the testimony. Again, the focus here today is not on blame, but on openness, trust, and ultimately treatment. And obviously, lay people following a case like this ask themselves, as I do, what standards do we apply as we receive treatment from medical professionals? What standards do medical professionals themselves apply?

That's a subject, thinking about the widespread use during this period of this radium rod treatment up the nose, which now, as we look back at it, seems primitive and dangerous, but at the time obviously was widely accepted in the profession. I'm going to leave the answer to that question to another hearing.

And now we look forward to the response of this panel to the questions, as Dr. Ducatman said, that have been raised here about concerns and about what the Federal Government agencies can do to spread the word of the potential problems, but also really to launch the kind of epidemiological study that we think is necessary here to answer the questions.

Dr. Mather, we'll begin with you.

STATEMENT OF SUSAN MATHER, M.D., ASSISTANT CHIEF MEDICAL DIRECTOR, ENVIRONMENTAL MEDICINE AND PUBLIC HEALTH, DEPARTMENT OF VETERANS AFFAIRS

Dr. MATHER. Thank you, Mr. Chairman. I'm pleased to be here today to provide VA's testimony regarding the health effects of radium treatments for aerotitis media.

Senator LIEBERMAN. I've been a little bit undisciplined here today because of the nature of the proceeding. Generally we try to limit the opening statement to five to seven minutes. If each of you can do that, it would be appreciated, and we'll print your full statements in the record.

Dr. MATHER. We share your concerns for the health and well-being of the veterans who received this kind of treatment during their service, as well as their families. We very much appreciate your diligent efforts on their behalf, and especially for holding these hearings, which have allowed us to hear very compelling testimony this morning.

The use of radium nasopharyngeal irradiation for the treatment of aerotitis media in military personnel was common during the 1940s and 1950s, as we've heard. The treatments were aimed at shrinking lymphoid tissue blocking the Eustachian tubes and thus helped to prevent the occurrence of ear problems following pressure changes. While the treatment has since been discontinued because of concerns about long-term health effects and newer alternatives for treatment, it was at that time an accepted medical practice.

We have discussed the issue with both Department of Defense and Department of Health and Human Services officials, and we have reviewed the scientific publications related to the issue, including the two very large-scale controlled studies that have been referred to today. The first was by Sandler. She studied children treated in the United States and found no increased overall cancer risk, but increased risk of developing benign and malignant head and neck tumors among exposed individuals.

Another paper from the Netherlands, which included both children and adults, found no increase in mortality rates due to cancer. These studies indicate to us that questions remain regarding the possible cancer risks associated with this treatment.

Senator LIEBERMAN. Excuse me. The study from the Netherlands, which I've seen referred to in the literature, I presume that was done there.

Dr. MATHER. Yes.

Senator LIEBERMAN. In other words, that this treatment was used in Europe as well as here during that period of time.

Dr. MATHER. It was. It was common in Europe.

As a result, VA has been in contact with the Submarine Survivors Group, and we have received the names of some of the submariners and airmen reported to have received radium treatments. We are attempting to locate these individuals' military personnel and medical records, to determine whether information relating to their radium treatments is documented in these records. This will assist in determining the feasibility of an epidemiology study. Documentation of the treatment of the subjects is essential for any study to be done.

A mortality study would probably be the first to be considered because the suspected health outcomes of concern from previous studies are cancers, and most of them are eventually fatal. Also the time period which has elapsed is sufficient for radiogenic cancers to have been manifested. Finally, a mortality study can be completed sooner, and is generally less costly than a morbidity study. If the mortality study suggests any other health effects related to radium treatments, a morbidity study can be designed to further evaluate these health effects.

We have taken also steps to assist veterans. Initially veterans benefits counselors staffing VA's toll-free information telephone services may not have been fully advised about the concerns of submariners and airmen and specific issues surrounding nasopharyngeal irradiation. However, this situation was corrected last spring, and information about how affected veterans can apply for disability benefits and VA medical treatment has now been disseminated nationwide.

Senator LIEBERMAN. If there's a veteran out there watching this hearing on C–SPAN, and remembers having had this treatment in the Air Force or the Navy, and they go to the local VA, do I understand correctly that they can receive at least, at first a preliminary investigation to see whether there's any problem resulting from the treatment?

Dr. MATHER. At this point in time, that is our plan. They can apply for benefits because health care is a benefit, and they would apply for benefits based on this exposure. There may be some eligibility problem if they have no actual disability but just want to be checked out. There may be some problems in getting outpatient care. But we're working on that.

Senator LIEBERMAN. And the problems are what?

Dr. MATHER. Since we're a disability based system, when you apply for medical care, you need to have some problem. So if you're just coming to be checked out, that's generally not available as a benefit. There is a problem in doing surveillance within the existing VA system.

Senator LIEBERMAN. But you're trying to work it out so that they can receive at least that preliminary exam to determine whether they have a problem?

Dr. MATHER. Yes. It may require enabling legislation.

Senator LIEBERMAN. Let me know if that's so.

Dr. MATHER. Identifying information and exposure information are taken by veterans benefits counselors and forwarded to the Department of Defense for tracking and further follow-up. Veterans benefits counselors assist veterans in filing claims for service-connected compensation, medical treatment and other services. VA is committed to assisting any veteran who believes he or she may have been injured by exposure to ionizing radiation, by any experimental medical care involving radiation or any other treatment or examination.

Of the over 1,500 reports of calls referred to the Veterans Health Administration from the national hotline, only seven specifically mentioned these radium treatments. Since January 1994, VA's radiation help line has referred to DOD 520 cases where veterans allege that they have undergone experimental treatment during military service. Although separate statistics have not been maintained on cases involving nasopharyngeal irradiation, the number is believed to be quite small.

That concludes my formal statement, Mr. Chairman. I would be pleased to answer any questions.

Senator LIEBERMAN. Thank you. We'll come back, after we hear from the rest, with some questions.

Dr. Smith, welcome. Again, Dr. Smith is from the Centers for Disease Control.

STATEMENT OF JAMES M. SMITH, PH.D., CHIEF, RADIATION STUDIES BRANCH, DIVISION OF ENVIRONMENTAL HAZARDS AND HEALTH EFFECTS, NATIONAL CENTER FOR ENVIRONMENTAL HEALTH, CENTERS FOR DISEASE CONTROL AND PREVENTION, ACCOMPANIED BY DR. DALE P. SANDLER, M.D., EPIDEMIOLOGY BRANCH, NATIONAL INSTITUTE OF ENVIRONMENTAL HEALTH SCIENCES

Dr. SMITH. Thank you, Mr. Chairman, and good morning. I am Jim Smith, Chief of the Radiation Studies Branch at the Centers for Disease Control and Prevention. Accompanying me today is Dr. Dale Sandler from the National Institute of Environmental Health Sciences.

CDC is pleased to have this opportunity to discuss with you the potential health effects, possible future studies of nasopharyngeal radium irradiation treatment. CDC has compiled reports about these treatments, which were apparently an accepted medical practice in the forties and fifties. Most reports were about its use in children and in military personnel.

The goal of the treatments, as we have heard, was to reduce swelling of enlarged lymphoid tissue. That's primarily the tonsils and adenoids in the nasopharynx, that's the passage in the back of the mouth where the nasal passages enter the oral cavity. This localized swelling was thought to cause hearing loss, especially in children, and a condition known then as aerotitis media in some people.

As we have heard, aerotitis is a group of symptoms, including bleeding from the ear, pain and rupture of the eardrum. It is caused by changes of surrounding or ambient air pressure.

The typical radium treatment was performed using two metallic applicators containing radioactive radium. The applicators were inserted through each nostril and placed near the opening of the eustachian tube for approximately 10 minutes. Radium treatments were also used by the Army and Navy during World War II for treating aerotitis, since its condition caused many divers and fliers to miss missions.

In the forties, when these radium treatments first came into use, many physicians thought it best to use the procedure to treat conductive hearing loss in childhood, before the loss became irreversible. The treatments were also advocated to prevent other problems, such as recurrent middle ear infections, and even sinusitis.

Safety concerns about the treatment in the late forties were normally about ulceration, burns, damage to bone and soft tissue, as well as cancer. Concern about the cancer grew when reports of thyroid cancer following X-irradiation to the head and neck began appearing in the literature in the fifties and sixties. The radium treatments were finally discontinued during the sixties, due to these concerns about radiation-induced cancer, and because of the availability of alternative treatment.

Two studies of children who received radium treatments were published in 1982 and 1989, with conflicting results. The first, conducted by Dr. Sandler and her colleagues, found an increase in head and neck cancers based on four cases out of 904 exposed subjects. The second study, by Verduijn and colleagues in the Netherlands, found no significant difference between the treated and the control group.

Based on what CDC has learned to date, it may indeed be possible to perform a meaningful epidemiologic study of people who received these treatments. Now, by meaningful, I mean a study designed with rigorous scientific methodology, with an adequate number of study subjects, so that the ultimate outcome of the study is convincing one way or the other.

Such a comprehensive epidemiologic study is likely to be very difficult and complex. The study would involve identifying a group of people who received the treatment in the forties and fifties, and a similar group of people who didn't receive the treatment, and then tracing and comparing the medical and health experience of all subjects. The identification and tracking of people from records of 40 to 50 years ago of course would be challenging.

Furthermore, because of the occurrence of the various types of cancer may be rare, missing just a very few cases, perhaps one, two or three cases, could have a major impact on the results of the study. We believe, therefore, that it's very important to undertake a feasibility assessment before any major resources are committed to a comprehensive epidemiologic study. I would point out that even a feasibility assessment at this time would require resources we do not currently have.

Senator LIEBERMAN. What would be involved in a feasibility assessment?

Dr. SMITH. A feasibility study consists primarily of looking for the clinics, offices, and the hospitals where these procedures took place, seeing if there are records available and not lost or destroyed, then looking into the possibility of finding these people, and looking into the medical and health status of people from that time up to the present time. If they died in the meantime, trying to find this information from death certificates, which we know would be very difficult.

Senator LIEBERMAN. Death certificates are not informative, are they?

Dr. SMITH. Not very informative. For example, one of the things you would want to look for in a study like this is the occurrence of thyroid disease or thyroid cancer. Now, of course, that has a low mortality, thyroid cancer itself. Only about 10 percent of the people with thyroid cancer actually die.

So someone may die, and on their death certificate, it lists a cause of death that has nothing to do with thyroid cancer. But yet, here's a person that had thyroid cancer, and we didn't find that out from the death certificate. But that's a good question, and represents the kinds of complications that one would get into.

Senator LIEBERMAN. So the feasibility study that you're talking about, as a precondition here, would be to find out whether it's feasible to obtain the necessary records and conduct the study.

Dr. SMITH. And track the people.

Senator LIEBERMAN. And you're talking about civilians in this case?

Dr. SMITH. Well, actually, I'm talking about generally, how to do a study like this. But in particular, the children may be even more difficult, since a lot of these were done, I understand, in private offices and clinics, and may not have the records that we would have for military personnel.

Senator LIEBERMAN. Dr. Mather, you were talking about the mortality study, am I correct?

Dr. MATHER. As a first step.

Senator LIEBERMAN. As a first step. And basically that would be to try to identify people that had this treatment, and then go back and look for death records, death certificates, and determine whether there was any significant incidence of related causes of death.

Dr. MATHER. That might be simpler than a morbidity study, because you have to identify the person and then follow, and their health records might span 40 years in different towns.

Senator LIEBERMAN. Yes. And again, the purpose here is to determine whether there's something serious to worry about that would then affect the action of the people who had this treatment, that is, that they should aggressively seek out medical care, preventive medical care. Is that the way you see it?

Dr. SMITH. Well, you would define up front, in an appropriate epidemiologic study the kind of endpoint, the kind of adverse health outcomes you're looking for. You just want to make sure that in your tracking of people and looking at medical records, for example, and interviewing people, medical examinations, that you have a good chance of finding out information about these things the study is seeking.

As a point of reference, Senator, CDC is conducting, under contract to the Fred Hutchinson Cancer Research Center, a study of people exposed during the forties and fifties to radioactive iodine emissions from a nuclear facility in Washington State. To complete this major study, more than 3,000 people will be traced, located, interviewed, and medically examined. This study is requiring approximately $17 million, three full-time positions at CDC, 40 contractor staff, and about eight years to complete. The pilot phase of the study has taken about two years.

In conclusion, Senator, CDC would certainly be willing to provide consultation to the Department of Veterans Affairs and the Department of Defense as they pursue the feasibility of a study of military personnel exposed to this treatment. An epidemiologic study of children who receive the treatment of course is a separate issue, and would require substantial effort even to determine feasibility.

Then if a comprehensive epidemiologic study indeed proves feasible, we expect it to be a very complex undertaking, requiring significant effort and resources that would need to be sustained over several years. Mr. Chairman, this concludes my testimony. I am submitting more extensive written comments for the record, and I would be happy to answer any questions.

Senator LIEBERMAN. Dr. Smith, am I correct in assuming that the study at Hanford that you describe involves a smaller population than received these radium rod treatments?

Dr. SMITH. Well, you know, we really don't know how many. Looking for example at the children right now, we really don't know how many children were exposed to these treatments.

Senator LIEBERMAN. To the radium rods?

Dr. SMITH. Yes. There are about, incidentally, a quarter of a million people who lived in the Hanford area during the forties and fifties. We are studying a cohort, or a group of about 3,000.

Senator LIEBERMAN. Okay, so the numbers might be comparable. But we've heard estimates as high as 400,000 for people exposed in the radium rod treatment. I assume also, just by way of comparison, that generally speaking, the exposure was more diffuse, if I can use that term, to the people in Hanford than the rods.

Dr. SMITH. Perhaps a better term than diffuse would be prolonged. Because those emissions occurred over a period of a few years, as opposed to treatments like this, which are more acute.

Senator LIEBERMAN. Okay. I thank you for your testimony. I have some questions I want to come back to after we hear from the representatives of the Defense Department. I've got Major General Buethe next. Have I got the pronunciation of your name right?

General BUETHE. It's Buethe.

Senator LIEBERMAN. Buethe, okay. Please.

STATEMENT OF MAJOR GENERAL ROBERT A. BUETHE, JR., ACTING SURGEON GENERAL, U.S. AIR FORCE

General BUETHE. Thank you, Senator. It's a pleasure being here. I'll make a very brief statement concerning the Army Air Force's involvement in irradiation, it became the United States Air Force, as you know, later on in that decade.

During World War II, a large number of aviators developed a condition known as otitis media, as previously mentioned. It is an inflammation of the middle ear caused by atmospheric pressure changes that aren't usually cleared through the eustachian tube. This was a big problem for the Army Air Force at that time because of the rapid pressurization or depressurization of the middle ear because of combat aircraft and the rates of upper respiratory infection, colds and things of that nature in the area where we were performing the combat, namely the U.K. and Italy.

Some flying personnel experienced this condition on a recurring basis, leading to subsequent grounding for days to weeks. In one report that we have, it was stated that one-third of our armed forces or crew members at that time were grounded at one time or another for this very condition. It was a real problem in management of the crews.

Nasopharyngeal irradiation with the radium rods was one treatment option. Others were used, such as proper positioning, clearing the ears, antihistamines or decongestants, prior to this being selected as an option. We think that the Army Air Force patients treated in World War II are approximately 7,000.

It is important to note that the nasopharyngeal radiation treatments were considered a standard practice, obviously, and people providing this treatment in the Army Air Force at that time all were trained at Johns Hopkins University, and all were otolaryngologists.

There is no consolidated listing of patients who received the radium rod therapy. Some individuals have identified themselves to the Department of Energy's ionization radiation hotline. In such cases, it may be possible to locate the serviceman's medical records and to confirm that treatment.

It is our intention in the United States Air Force to fully support the efforts of the Department of Veterans Affairs and study any complications which may be associated with this form of therapy. Thank you.

Senator LIEBERMAN. Thank you, General. I'll have some more questions.

Admiral Koenig, thank you for being here.

STATEMENT OF REAR ADMIRAL HAROLD M. KOENIG, DEPUTY SURGEON GENERAL, U.S. NAVY

Admiral KOENIG. Good morning, Mr. Chairman. I have also prepared a written statement and ask that it be included in the record.

Senator LIEBERMAN. It will be.

Admiral KOENIG. I have just a few comments. First of all, I'd like to state that I have a very particular interest in the potential consequences of nasopharyngeal irradiation. First off, my specialty in medicine is pediatric hematology and oncology, taking care of children with blood diseases and cancer.

Second, is that I, too, received this treatment as a child for chronic tonsillitis. And ever since I went to medical school and began to learn the dangers of radiation, it's something that's always been on my mind. Fortunately, all my examinations to this point have shown that I have suffered no adverse consequences.

Senator LIEBERMAN. Let me interrupt you, and I appreciate your making that personal statement. This may again be helpful to anyone who's watching or hears about this hearing and this problem. Being a doctor, did you ask for some special exam when you went in, knowing that you'd had this treatment?

Admiral KOENIG. When I go in for my annual physical examination, I let the ENT doctors, the otolaryngologists, know that I had that exposure as a child. They take extra care checking out my nasopharynx to make sure that there's nothing in there that shouldn't be there.

Fortunately, I've never been a smoker, so I don't have that complicating factor, which is going to be a hard one to separate out, I'm afraid. My thyroid has been scanned and it's okay. And it's been in excess of 40 years since I've had that treatment.

Senator LIEBERMAN. So those are the two things that you'd ask if you were concerned about this and had the treatment, for a medical review of the thyroid and of the nasopharyngeal passage?

Admiral KOENIG. That's what I as a physician would ask for. I think what we need to do is get the people of our Nation just to bring to the attention of their physicians that they had this treatment as a child and we need to educate our providers in our nation that people who have had that exposure may have some risk that the rest of the population doesn't have. We don't have the answers, of course, and that's already been covered during the hearings.

To get down to where the Navy is with this, radiation therapy for aerotitis media was the standard clinical practice in both the United States and other medically advanced nations for several decades, beginning back in the 1930s. The Navy used it for many years to treat members of the submarine service, who always have been and hopefully always will be volunteers, during World War II, to reduce the frequency of pressure-induced damage to their inner ears and their eardrums. An inability to relieve this pressure would have been disqualifying for these individuals, and impaired our Nation's ability at that time to man its submarine force.

You have asked us how many submariners were treated. Unfortunately, despite extensive searches, we have been unable to locate logs, journals or other information which would document the number of individuals who may have received radium nasopharyngeal treatment.

Mr. Chairman, the Navy stands ready to assist you in addressing health questions that have been raised. We will work closely with the Department of Veterans Affairs in investigating this question, and will support their efforts in any follow-on epidemiologic study.

Senator LIEBERMAN. Thanks, Admiral.

Having heard your testimony, I think I know your answer to the first question I'm going to ask. But am I correct in concluding that all of you agree that there's enough of a problem to ask some more questions in a study and to try to alert people who have had this treatment to ask for the kind of exam that Admiral Koenig has asked for himself? Is that a fair conclusion? Does anybody disagree?

Dr. Smith?

Dr. SMITH. Well, I'm not sure I would disagree entirely. But I'm not sure, Senator, that we have sufficient information at this time to let our medical colleagues throughout the country be alerted to any potential problem here. The studies that have been done, the two major ones that I referred to, again are conflicting and based upon very few numbers.

So we really can't be sure that at least for cancer that there is a problem. That's the reason we would ask that one thinks carefully about the feasibility of doing an epidemiologic study, a comprehensive one, a meaningful one, that could indeed answer, or at least address, that question.

Senator LIEBERMAN. That surprises me. You don't think that there's enough data here, you don't think there's enough data presented to raise concerns that ought to be studied, am I correct?

Dr. SMITH. Yes, I think there are concerns here that need some further discussion and elaboration.

Senator LIEBERMAN. But not enough, at least in your opinion, to advise doctors around the country to examine patients who tell them that they had this treatment, to see whether there's any problem?

Dr. SMITH. I would feel more comfortable that if at least, the CDC, with the National Institutes of Health, Department of Veterans Affairs, Department of Defense, perhaps some medical groups, physicians of certain specialties, some of the professional groups could sit down together and discuss the issues around this.

I think one should be careful about sending out medical alerts without knowing with some confidence that there is a risk, and then being able to make some specific recommendation about what to do about those risks, what to screen for.

Senator LIEBERMAN. Does anybody on the panel want to take issue with that?

Yes, Admiral.

Admiral KOENIG. Well, Dr. Smith said he agreed with this for the most part, and he approached it a little bit tangentially. And I think that we need a lot of epidemiologic work to be done before we go out and frighten people.

Senator LIEBERMAN. Right.

Admiral KOENIG. But at the same time, I think that people who know they received this treatment shouldn't just forget it. There are a lot of hazards that we're exposed to as we go through our life experience. When we become aware that some of them may have been dangerous, I think it's worth calling that to the attention of our health care provider, and that our health care provider then take the necessary steps to do at least an initial evaluation.

And the things we're asking people to do are pretty simple, like feeling the thyroid gland. All providers are trained to do that, and certainly to have a look inside the nasopharynx to make sure there is not something in there that shouldn't be there. That isn't very hard or very expensive to do. That can be done by family physicians or general internists, or any primary care provider, really.

Senator LIEBERMAN. Yes. Go ahead, Dr. Sandler.

Dr. SANDLER. I was going to say that in the late seventies, there was at NIH, the cancer institute had a consensus conference on the other forms of head and neck irradiation. The population that were treated were showing up with thyroid cancer.

And as a result of that consensus conference, the medical alert was issued to physicians, and a brochure was produced for the general public, alerting them to potential risks from head and neck irradiation, and suggesting just that when somebody knew they were treated, that they should bring this to the attention of their physician and have their thyroid examined, which is a fairly simple thing to do.

In the bulletin that went to physicians, the nasopharyngeal radium irradiation treatments were mentioned in passing. But the larger focus was on x-rays.

Senator LIEBERMAN. Was this the same notice that went out in 1977 from Johns Hopkins or was this was something different?

Dr. SANDLER. No. The notice from Johns Hopkins was specific to the work that was done at the Health Department in Maryland. They ran a prevention of deafness clinic, where they screened school-aged children. So that was specific. Actually, I think it was all related. But there was a national conference and actually, there were two conferences, where the second one affirmed the recommendations of the first one. I have a copy with me of the brochures that were produced. I don't have enough copies to share, but I would happy to have you take a look at it.

Senator LIEBERMAN. I'd appreciate if you would make that available to the staff.

Let me focus in here on what we can do together to try to deal with this. Because we've got both medical and civilian personnel, and we've had some clear expression of interest by most of you in trying to deal with this problem.

How can we get you together to take the steps that are necessary to perform the study that we're talking about? Will the human radiation working group that the President convened in the White House, is that a forum, can I ask you today to get together? I think we've got a problem here.

And again, I'm a layman, I'm responding to a letter that came in, concern by a group of my constituents who happen to be submariners and children treated by this particular doctor, who are now, as Ms. Kenneally, adults and worried about health effects. So we're asking questions here.

And we've got to figure out a way to break through the normal red tape and institutional obstacles, and see if we can get you all working together to do this kind of study. That's really what I want to hear.

Dr. Mather?

Dr. MATHER. I think you've already taken the first step, Senator, in getting us talking together. And I feel that there is a commitment on the part of everyone involved to try to get to the bottom of this. The first step, though, will be to see if a study is feasible in the sense that can you identify a population of exposed people with documented exposures.

And I think that step we're already taking. The military has been cooperative, and we're working with Mr. Garrity's group to go at that question of feasibility and hope to have that answered within a month or so. Then we'll want to be planning the study. I know there is some controversy about morbidity versus mortality studies. And I don't think that the two are mutually exclusive.

It's just from our standpoint, we can do mortality studies within existing resources, if we can identify the subjects, the exposed population. We probably cannot do morbidity studies, which are a lot more complex and more expensive, within existing resources. But if we can identify the population——

Senator LIEBERMAN. Right.

Dr. MATHER [continuing]. We can then identify controls. The control population isn't the problem. The subject population, we have to make sure, that we can document and really identify not a self-selected population, but a truly representative population from which we can then take a random sample.

Senator LIEBERMAN. Yes. And again, mortality obviously is a population that's died.

Dr. MATHER. A population that is dead. And of course, a mortality study will not pick up, for instance, the thyroid problems, because for the most part, they are not fatal diseases.

Senator LIEBERMAN. Yes.

Dr. MATHER. So there will need to be a morbidity study to look at that.

Senator LIEBERMAN. Just for the record, define what morbidity means in this case.

Dr. MATHER. Morbidity is illness. Mortality is death.

Senator LIEBERMAN. People who are sick with this now, or may be sick with it, or are sick and wonder whether they're sick because of this.

Dr. MATHER. Primarily all the illnesses which have occurred in the 40 years that a person has been alive, or 50 years, since they got the treatment.

Senator LIEBERMAN. Yes.

Dr. MATHER. What of those illnesses are in excess in the group that got radium treatments compared to a group, a very similar group who didn't get radium treatments.

Senator LIEBERMAN. Right. So, Dr. Mather, I appreciate your response. Is the VA prepared to take a leadership role here in continuing the dialogue?

Dr. MATHER. Certainly from the point of view of the veterans, who are our responsibility, and we take that very seriously. And I personally have a great desire to see additional scientific literature on this subject.

I, too, was offered radium treatments when I was a child. My father was a chemistry and physics teacher, and he said what's wrong with the old-fashioned way of just taking these adenoids out. And the ear, nose and throat surgeon, who had been one of his students, said, well, if that's what you want, Mr. Howard, that's what I'll do. And that's what he did, and I felt very, very put-upon at the time by my father, who was so old-fashioned.

Senator LIEBERMAN. Yes.

Dr. MATHER. But I'm grateful to him now.

Senator LIEBERMAN. You were lucky. But tell me again what you think can be done within the next month or two. You mentioned that time period.

Dr. MATHER. Well, we'll have some answer as to whether we can identify people who have been exposed.

Senator LIEBERMAN. In other words, whether the veterans, the VA records, and the Defense Department records allow you to do that. Okay. That's an important question. At different times, some of the witnesses have indicated there was concern about the availability of records. But you're going to pursue that now, and hope to have an answer for us.

Dr. MATHER. I mean, the ideal would be if there were a roster somewhere of all the people who had gotten these treatments. But I'm convinced that there isn't such a roster, so we're going to have to look at it from the other way. If we can identify people who were, who had documented exposure, then we can begin to look at rosters of the places where they trained, in the submarine schools.

Senator LIEBERMAN. Right.

Dr. MATHER. We can look at rosters of individual submarines they served on. And that sort of thing. We can go around from the back door trying to identify the group.

Senator LIEBERMAN. Again, with humility and respect, I'm responding. It does seem to me that the submariners are probably the most easily identifiable group to go with. Because I gather that most everybody went through this tank test, and so it's a more limited, by its nature, it was a select group, a relatively small group. So it seems to me it should be possible.

Dr. MATHER. That's our hope. We won't know until we look.

Senator LIEBERMAN. All right. Those are significant first steps, and I appreciate those. And I presume that you've got the cooperation of the folks at the Pentagon in that.

Dr. MATHER. Excellent cooperation.

Senator LIEBERMAN. That's good news.

To what extent has the work of the submarine survivors group been of help to you? Have you had a chance to review the records that they have?

Dr. MATHER. As soon as we learned through your staff of Mr. Garrity, we called him, and within hours I think he had gotten back to us, and within days had gotten us what we asked for: 24 people, the names and permission for searching the records for the documentation.

Senator LIEBERMAN. Why did you ask for 24?

Dr. MATHER. It was just a reasonable start. And we figured that if we could find documentation for 12, then the possibility of finding for a lot more would be easy. But 12 would give us a reasonable number. If we only find 6, well, that's still a significant number.

Senator LIEBERMAN. Okay. That then takes the first steps toward the study. I do hope, and again, I'm certainly prepared, and I think others in Congress would be, to work with you on this.

I don't mean to minimize the cluster, but within the hundreds of millions of dollars that the agencies have received from Congress, I hope you can find the money necessary to carry out this study. It does seem to me that it's a moral responsibility of the Government in whose service these sailors and Air Force men and women were, to at least check to see whether they have reason to have fear.

I suppose the second question, then, is, how would you get a notification out to people who might have received this treatment? One part obviously is to find out exactly who received it and let them know directly. I know that there are other publications that veterans receive regularly.

Is it possible to both through official governmental publications and through veterans groups to at least immediately, without again wanting to create panic, raise the flag of warning that this may be a problem, and they ought to ask when they go for a medical exam for the same kinds of relatively simple exams that Admiral Koenig asked for.

Dr. Mather?

Dr. MATHER. Yes, certainly it's possible in the service organizations, DAV and American Legion and VFW, the big three, anyway, are always interested in those kinds of outreach activities. And I think once we determine that there is a problem, then a mechanism exists for identifying individuals if we have their names through NIOSH and the Internal Revenue, they will provide current addresses of people who have had dangerous environmental exposure, or potential environmental exposure. So we do have that way of identifying and contacting individuals.

Senator LIEBERMAN. I would really urge you to do that, and I would urge you to do this in a way that doesn't unduly frighten people. But we're at a point, I do think, where we do have a responsibility to put people on some kind of notice that this may be a problem, and through the existing network of both governmental and non-governmental publications that go to vets all the time, I hope you can take a lead in giving that kind of notice.

Dr. MATHER. I think that's where a group such as Dr. Smith suggested, of civilian physicians, public health experts, CDC, and VA and the military getting together would be useful. Because a non-inflammatory statement that doesn't panic, that doesn't scare somebody, is not something that is real easy to draft. And I think we can identify the expertise we would need, but we're certainly willing to take the lead on that part.

Senator LIEBERMAN. Okay. Let me, Dr. Smith, read you something. The Secretary of the Cabinet, Christine Varney, who I've corresponded with on this question, because she's involved in the human radiation working group that the President established after Secretary O'Leary's disclosures, wrote to me in May. And she said, and I don't know the person, but she said that HHS had recommended, so I don't know who at HHS, that:

> Individuals who received therapeutic doses of radiation or radium application to the head, neck or upper chest for various non-malignant conditions are at increased risk for developing cancer of the thyroid, and to a lesser extent, of the salivary glands and other structures of the head and neck. As such, any individual, civilian or military, who has been treated with radiation to the head, neck or upper chest, should contact a physician and ask for a complete examination of the head and neck. Following this initial exam, regular examination should occur every one or two years. It is important to be examined by a physician whether or not a lump can be felt in the throat or neck. If a lump is discovered between examinations, it should be checked by a physician immediately.

Again, I don't know who at HHS said that to Ms. Varney. But again, it's not a panicky statement. It says, and I want to go back to this part of it, it says, are at increased risk, it just says increased risk, for developing cancer of the thyroid, and to a lesser extent, salivary glands and other structures of the head and neck.

So isn't that enough to give some carefully worded notice to physicians around the country?

Dr. SMITH. Well, Senator, that sounds similar to what the 1977 bulletin said, referring to general radiation to the head and the neck. So that is something that physicians were alerted to in the late seventies. It's my understanding that in medical school curricula, physicians are pointed out the potential dangers, the risks, from radiation to particular parts of the body.

Perhaps what needs really to be done, and this is just a thought, and again something that would deserve a lot of discussion within CDC, National Institutes of Health and other interested agencies, but perhaps an update of the 1977 bulletin might be considered.

I was just cautioning earlier about focusing in just on the nasopharyngeal radiation, since there are other——

Senator LIEBERMAN. Aha. Okay. I understand you better now.

Dr. SMITH [continuing]. Radiations. For example, if I might also add, most everyone on the panel has referred to particular stories of their own. When I was 14 years old, I received X-irradiation to the face for acne. So there really have been a variety of different ways that people have been exposed to radiation to the head and neck.

I was cautioning earlier about just focusing in on the nasopharyngeal region.

Senator LIEBERMAN. Just out of curiosity, when you get your regular medical exams, do you ask for anything a little bit extra?

Dr. SMITH. Oh, yes, I absolutely do. I always point out to that physician that I have had that irradiation. And that may have helped the physician in one case diagnose that I had hypothyroidism, which could have been due to that irradiation. I really can't be sure.

Senator LIEBERMAN. Right. Well, that's very important. I didn't know this about either one of you, and I appreciate your mentioning it. And again, it's coincidental, and I don't know whether your hypothyroidism is coincidental, but the fact that you two have had this experience, and that you've asked for a relatively simple extra part of the normal medical examination, and that's really all we're asking that anybody else who knows that they had this treatment do as a preventive step.

So I guess when I hear you saying now, and I appreciate it, I hope you say you'll recommend, but that CDC ought to essentially reissue that 1977 notification to doctors around the country. And I understand what you were reacting to before is the more limited, that wasn't my intention, but I probably phrased it incorrectly, the more limited notice I was talking about. Obviously, since 1977, that's 17 years, there's a whole new generation of doctors out there, and others who have forgotten it, and I think it would be really helpful.

Dr. SMITH. Well, Senator, I assure you that I would be very willing to bring this question back to CDC so we can discuss the issue there and with our colleagues at the National Institutes of Health.

Senator LIEBERMAN. I appreciate that. And I'd like you to let me know what the decision is.

Dr. SANDLER. I'd just like to say for balance that the consensus is on thyroid cancer from all of the head and neck treatments, most of which resulted in a dose to the thyroid that was about 10 times greater, dose to the thyroid. And so all of the studies that have been done have focused on thyroid cancer, and we have very little data on the other cancer, other than the small report that I wrote.

So thyroid cancer is probably not the main focus of concern for this particular treatment. So while it's important to reissue these guidelines, it may not be all of the story.

Senator LIEBERMAN. It may be that you'll want to alter some of the wording on the guidelines, you're saying?

Dr. SANDLER. Well, I'm saying we don't have the data to tell us what the other ones might be, but that the risk for thyroid cancer for this particular treatment, if they just based on dose, it's likely to be lower than from the other head and neck treatments that are being studied.

Senator LIEBERMAN. Okay. Stewart Farber is bursting to get into this, and I don't want to frustrate him, because he's been such a leader. So why don't you find your way up to the table, just pull your chair up and sit next to General Buethe. And we're going to wind up the hearing in a moment or two. But go ahead, Stewart.

Mr. FARBER. I just wanted to make one comment in regard to what do we know scientifically about the effects of radium, between the Sandler study and the Verduijn study that followed some years later.

But it's a very important distinction. The Verduijn study was of children as irradiated in Europe. They were using 25 milligram irradiators versus 50. The radiated for much less time. The average dose, as reported by the authors of that study, were something on the order of—I'm going by memory—700 milligram hours to the average child followed. The average total irradiation, radium exposure to the U.S. experience, by their calculation, was 4,200 milligram hours.

So the European study was of radium as delivered in Europe to young children at about one-sixth the average exposure of the practice as it was handled in the United States. Therefore, that European study is not directly relevant. It's not the same level of exposure. And that has to be recognized as a fact, when we put the data on the table.

So that study does not describe anything about U.S. knowledge or experience or what the likely outcome is of U.S. radiation, radium exposure.

Senator LIEBERMAN. Dr. Sandler, do you want to respond to that?

Dr. SANDLER. Well, that's correct, they used, the applicator was half the size, and they generally only irradiated using one side, through one nostril. So the treatment was a lot lower, and not repeated as frequently.

There's one other small study that was done that was sort of buried in the context of a larger study of head and neck irradiation, where they looked at 400 kids treated in the U.S. with about half the dose that they were using in Western Maryland. And in that study, there was, I think there were two head and neck tumors, but nothing that was statistically significant, and very difficult to attribute to anything.

Senator LIEBERMAN. Right. Okay, I want to thank all of you for your response here today. So from this panel, I conclude that the representatives of the relevant Federal agencies agree that there are questions to be asked and answered, and that in the reasonable exercise of diligence and responsibility, that we ought to be doing whatever we can to notify medical professionals in the first instance.

And then I suppose as we go on, and through informal channels at least, or in a preliminary way to notify veterans, in case they've received this treatment, to be alert, on the premise that the earlier you go to the doctor, the earlier a problem is determined, the more easy it is to treat a potential problem, whether it's from this or anything else.

And within a month or two, Dr. Mather, I look forward to hearing back from you about how your work is going with your colleagues in these first steps on the study, and Dr. Smith, I'd appreciate hearing back from you on the conclusion of CDC about reissuing in similar terms or exact same terms the warning or notification that was given to the medical profession.

I thank all of you for the response. This is a concern to me. I'm going to stick with it. I look forward to working with you on it. Again, I want to thank Stewart Farber, Jim Garrity, Dr. Ducatman, Ms. Kenneally, everybody else who has had the courage to focus in on this, and to help us fulfill our responsibility.

The hearing record will be open for an additional three weeks for any additional testimony that anyone might want to submit or any questions that we might have for the witnesses.

With that, I thank you once again, and adjourn the hearing.

[Whereupon, at 12:18 p.m., the subcommittee was adjourned, to reconvene at the call of the Chair.]

[Statements submitted for the record and responses to post-hearing questions follow:]

WEST VIRGINIA UNIVERSITY
SCHOOL OF MEDICINE

August 29, 1994

Statement of:
Alan M. Ducatman, M.D., M.Sc.
Professor of Medicine
Director, IOEH

Presented to: United States Senate Subcommittee
on Clean Air and Nuclear Regulation

My name is Alan M. Ducatman. I am a board certified internist and board certified occupational physician. I am also a Professor of Medicine at West Virginia University and Director of the Institute for Occupational and Environmental Health there. I am a Trustee of the American Board of Preventive Medicine, and I sit on the editorial boards of the usual scientific peer review journals.

From 1983-1986, I was a Lieutenant Commander at the US Navy's Environmental Health Center in Norfolk, VA. I spent the happiest and most productive professional years of my life in the Navy, and worked with the finest and most dedicated colleagues imaginable. I left the Navy to accept a position at Massachusetts Institute of Technology. While still at MIT in Cambridge, Massachusetts, I coauthored in 1990 with Mr. Stewart Farber a brief letter to the New England Journal. The letter called attention to the need for study of a large population who had received radium nasopharyngeal treatments.

Mr. Farber alerted me to the historic story of these treatments in military veterans, especially submariners, and he asked me if it was appropriate that this population be surveyed for health effects of those treatments. The treatments consisted of insertion of a small device holding radium, introduced through the nose into the back of the mouth, for the purpose of using radiation to shrink tissue around the opening of the Eustachian tube. This was thought to prevent barotrauma from rapid pressure changes, an operational problem of dunk-tank training, and of high performance flying. A substantial local radiation dose is required to kill cells and affect tissues in this way. Individuals so treated received multiple radium exposures, usually of 10-15 minutes through each nostril. The question prompted both serious soul-searching and literature review on my part. After considerable thought, I told Mr. Farber the following: yes, the exposed population needed to be surveyed, for a host of good reasons.

Allow me to reiterate those reasons. They have not changed.

1. Most important, we do not know whether these treatments caused excess head and neck disease among those who received them. Pharyngeal cancer and salivary gland cancer are obvious questions and there are others as well. The several studies in existence are too small, are different in design, and give contradictory results. A definitive study is needed.

2. The affected Navy population appeared large enough to expect that a well-designed study could give us an answer. We knew that military aviators were also treated, but were unsure of the size of the treated aviator population. We suspected it might be even larger than the submarine group, but had no data. Combining affected populations, assuming the aviation population was also large, it appeared certain that an adequate study could be done.

3. This was obviously a substantial local radiation exposure. Mr. Farber is a health physicist, I will let him characterize and compare the exposure for your benefit. In the affected areas, it is much larger than most occupational exposures.

4. The data will be important to others so treated and for our understanding of radiation health effects.

5. The treatments are no longer acceptable for the purposes used. Review articles disavowing the acceptability of the treatments for these purposes were published in the 1950s.

6. Military populations received these treatments as an integral part of their service. Treatments were not experiments, but they were not intended for the normal health care of the military population either. The treatments were for operational, not medical requirements. They were intended to permit training or operational activities such as dunk tank exercises.

For these reasons, I felt and feel that the treated population deserves medical surveillance. Our letter was published by the New England Journal in early 1992. Understanding of the significance of our letter came slowly, and was complicated by irrelevant confusion with shipyard studies (where the exposure dose is a fraction as large and difficult to determine) and with prejudgments concerning absence of excess risk. A unique aspect of these medical radium exposures is that we can model and determine the radiation doses received with a high degree of confidence. Individuals either received treatments, or they did not. For those who received treatment, exposures can be understood quite well. This situation stands in stark contrast to the much lower levels of exposure received in the typical radiation workplace, especially in the absence of environmental monitoring.

My analysis from 1992 suggests no prejudgment about study outcome. There are anecdotal stories and a small study by Johns Hopkins also suggesting a problem. Excess brain cancer and thyroid disease were found by Johns Hopkins researchers in a survey of fewer than 1000 children who received radium treatments for conditions such as chronic ear infections. These findings give cause for concern, but do not answer the outstanding questions. I do not know if a larger, excellent study of nasopharyngeal-radium treated patients would show excess risk, or not. No one else knows either. What I do know is how to find out. That is why we do studies.

To obtain answers, a study must be done to highest attainable standards of epidemiologic excellence. That implies identification and accurate confirmation of exposed populations, with subsequent identification and confirmation of their individual and summary disease outcomes. Experts from several disciplines should be involved. Ideally, appropriate federal agencies such as the Centers for Disease Control and Prevention including National Institute for Occupational Safety and Health, and the National Cancer Institute, would have input into any proposal. Capitol Hill is probably not the forum for the dry language of epidemiology, but the committee should understand the a priori interest in certain head and neck cancers, in hearing and balance problems, and in thyroid disease. The thyroid disease question was raised by the Johns Hopkins findings. The committee should also understand that there are many issues ranging from ascertainment bias to confounding bias, that make such study challenging.

Using informal data already collected, it should be possible to perform a feasibility study demonstrating whether or not a designed study can be conducted. Independent, expert panels are certainly appropriate for this mission, provided that the normal temporal effect on veteran mortality is kept in mind. An effective study that means to include living World War II veterans should not be delayed indefinitely. The reason for the suggestion of an expert, independent panel is simple. The affected veterans and the larger body of taxpayers deserve the comfort of knowing that any work done is excellent and any resources used appropriate and cost-effective.

Finally, I have a wry and partly non-scientific observation for the committee. Preliminary proof that the needed population data can be effectively gathered has came from a non-expert source, the veterans themselves, also represented here with us today. They won the Battles of the Atlantic, of the Pacific, and they planted the seeds that undermined the wall across Europe. I certainly would not want to tell them that we can not monitor their health status because good epidemiology is difficult. I certainly would not want to tell them the we can not mount an effective epidemiologic study, because it would not be true. We just have to decide if it is a priority. As you know, they have already begun to collect data, because no one who is an "expert" is doing it for them.

The effects of nasopharyngeal radium treatments are an appropriate topic for study. It is time to support the efforts of those so treated. It would certainly be appropriate to do this scientifically.

AMD/mk

WEST VIRGINIA UNIVERSITY
SCHOOL OF MEDICINE

September 12, 1994

Honorable Joseph I. Lieberman
United States Senate
Chair, Subcommittee on Clear Air and
Nuclear Regulation
Washington, DC 20510-6175

Re: Nasopharyngeal Radium Irradiation

ATTN: Murray Hitzman, Ph.D.

Dear Senator Lieberman:

I have several comments concerning the hearings you conducted concerning nasopharyngeal radium irradiation. You assured that the American people were served and their public health protected by their government. This would not have happened without your intervention. Hundreds of thousands of our citizens will have cause to be grateful. I am personally grateful in my role as a preventive medicine specialist.

We are not yet all the way to where we need to get, however. The hearings raised some areas of potential misunderstanding, and several speakers erected some artificial barriers to good medical surveillance and summary data collection for the affected population. My comments are intended to address these matters so that work may go ahead.

1. A radiation expert from the Centers for Disease Control discussed difficulties of "low level" ionizing radiation studies, and cited enormous attendant costs. The definition of "low level" ionizing radiation may be flexible, but it surely should not include the (approximately) 2,000 rad mucosal dose associated with military operational treatments.

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2. The high costs of the Hanford study were cited specifically as a deterrent. The Hanford comparison is indefensible. One problem at Hanford relates to long-term exposures and reconstructing/modeling dose. Another Hanford problem involves establishing geographic positions of populations in the relatively distant past. Neither of these expensive problems pertains to a proposed survey of military treated nasopharyngeal radium patients. The presence or absence of radium treatment is binary. Dose ascertainment is not related to extensive modeling. Once presence or absence of treatment is ascertained, the approximate exposure will be in one of several categories.

3. Reference was made to the need to identify entire groups from some source other than volunteer information. This would be a problem for common outcomes studied retrospectively, such as thyroid disease. For rare outcomes such as nasopharyngeal cancer, the question of bias can be dealt with in several ways. Alternative approaches (including multicenter case-control approaches) could adequately deal with selection and survivor bias. It is reasonable to perform a feasibility study of a prospective study of a self-identified population. Prospective study is also an approach to common outcomes such as thyroid disease. Provided exposure to treatment can be verified, bias would not be a major issue for subsequent outcomes of concern, particularly if case cohort methodology were applied simultaneously.

4. No one has considered querying the self-identified treatment group for the names of additional individuals who were also treated.

5. The Veteran's Administration should be commended for its positive attitude, but we should be cautious concerning its approach to designed studies. The "feasibility study" by the Veteran's Administration is not a feasibility study in any sense. By description, it is a review of up to 24 medical records for confirmation of exposure. If successful, it will not mean that a study is feasible. If unsuccessful, it will not mean that a study is infeasible. A real feasibility study would begin with the submarine veterans, progress to record linkage (relying in part on their knowledge) and identify presence or absence of ability to do record linkage. The estimated cost of real feasibility work is far more than the simple review of a dozen or two records, and less than the seven digit cost assertions of the CDC Radiation Health expert.

6. Implicit in the testimony of the CDC (and perhaps the VA) is a performance assumption not necessarily shared by others present. Their testimony implies that population study would be exclusively an internal government agency matter. Involvement of government agencies, including National Cancer Institute, National Institute of Occupational Safety and Health (of the CDC), the Veteran' Administration, the Department of Defense, and probably others, is absolutely necessary. I pointed this out in my initial testimony before your Committee. It is not sufficient, however. Others must be involved!

   There are two problems with an internal approach only. First is absence of credibility with the affected population. Involvement of academic centers is predictably essential for credible independence. Based on presented testimony, I also now believe that it is necessary for cost-effective approaches.

This leads to a proposal. A real feasibility study needs to be performed. It should designate a rapid time frame and should not cost less than $350,000. Its purpose would be to liaison with the various agencies and entities holding formal and informal records,for the purpose of determining if a population can be identified and records confirmed for subsequent study of military (or other) nasopharyngeal radium irradiation patients. The purpose of the feasibility study would be to document the presence of records, record linkage, and appropriate study design for an independent peer-review committee.

Sincerely,

Alan M. Ducatman, M.D., M.Sc.
Professor of Medicine
Director, IOEH

AMD/gsc

WEST VIRGINIA UNIVERSITY
SCHOOL OF MEDICINE

September 21, 1994

Joyce Rechtschaffen
Senate Committee on Environment and Public Works
SH-407
Washington, DC 20510-6175

RE: Hon. Joseph I. Lieberman
Request of Sept. 12, 1994

Dear Ms. Rechtschaffen:

Senator Lieberman posed three related sets of questions to me. A copy is enclosed. These are my responses; the questions are rephrased slightly for internal consistency:

What should an epidemiologic study cover?

1. Outcomes of interest should be divided into two categories: A) Mandatory B) Potential Additional Outcomes of Interest .

   A. Mandatory outcomes include: nasopharyngeal cancer, brain cancer (by anatomic site if possible), and thyroid disease including cancer (because of the original observation in the Johns Hopkins population).

   B. Potential additional outcomes of interest include hearing loss, vestibular problems, and sinus disease. These are plausible outcomes, but they are more difficult to quantify, and may be subject to confounding bias.

What federal agency should conduct a study?

It is not clear that a study should necessarily be conducted by a federal agency. Federal agencies are best prepared to structure the proposal process and to provide a forum which arrives at sharing pertinent information and arriving at consensus concerning goals. Federal agencies with an interest in this topic include National Institute of Occupational Safety and Health (part of the CDC), DOD, NCI, Veterans Administration, and others. Preference for a lead agency would be NCI or NIOSH. in cooperation with Veterans Administration. A good decision would require a preliminary planning scientific meeting, to be jointly sponsored. Such meetings are routine for federally sponsored population research.

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How should such a study be structured?

Now that coherent records no longer exist in a single place, study structure has to be the art of the possible. This implies identification of a coherent population, so that bias is minimized.

It should be noted that no definite design proposal will be realistic in the absence of a feasibility study. The feasibility study should attempt to identify personal records of submarine or aviator groups, for subsequent comparison to medical records if treatment records exist. Study designs depend upon feasibility findings. Possible designs include:

--- Historical prospective study.
--- Case Cohort study.
--- Multicenter case-control study (for common outcomes such as thyroid disease. Note that this design could include non-military nasopharyngeal radium patients.)

Should the study cover veterans and civilians? Should it distinguish between treatment populations by age or sex?

The study should include coherent populations with medical records. This will likely exclude many civilian patients. If a civilian treating physician's records still exist, then certainly that population should be followed. It is essential to distinguish between/among populations, by sex, present age, treatment age, and other routine demographic variables . (There is nothing wrong with summarizing data jointly, so long as they can also be distinguished.)

Should the submarine survivors group provide the basis for a study?

The answer to this question can not now be known, as no one has made any scientific effort to use these data. The implicit rejection of Submarine Survivors data by several of the experts who addressed your subcommittee is inappropriate. These data are likely to prove useful under several circumstances:

-- If there is unexpected, startling excess of some outcome, so that hypotheses can be refined.

-- If the memory of volunteers can be used to recapitulate personnel and treatment information, for the purpose of recreating cohorts within the larger population of personnel at risk. For example, we have used employees to identify entire worker cohorts. This might be done again for submarine or aviator trainee groups.

2. **Do physicians presently inquire about or initiate patient discussions concerning past medical history of nasopharyngeal radium radiation treatments?**

No. Most physicians never heard of this procedure. (A few experts in radiation medicine or otolaryngology may know of it, but even they generally believe that it was not commonly applied after the commencement of the antibrolic era.)

The treatment population is 400,000 against the background size of the entire adult U.S. population older than 30, so public health would be served most beneficially if recipients of this treatment could be taught somehow to self-identify to their physicians. This can happen if we can first inform them. An alternative approach is development of some accurate, affordable biologic marker of previous exposure. I know of no available science which permits us to do this. Thus, we are now left with encouraging physicians to make inquiries if we hope to identify individuals at potential risk.

3. **Can I explain why early notification may decrease the risk that these patients will become seriously ill?**

First, we do not yet know about the extent or existence of excess illness. So the utility of early notification is speculative. We should plan for the contingency that excess disease is possible. If excess disease exists, however, early detection may be of benefit. Potential benefits of early disease detection are illustrated by the success of cervical cancer screening. Screening (sometimes called surveillance) programs are intended to detect early phases of chronic diseases, and thereby mitigate their effects. For any screening program, it is appropriate to calculate the costs and benefits. This can not now be done for nasopharyngeal radium radiation treatments. We do not now know how much disease (such as nasopharyngeal, cancer or brain cancer) such a program would harvest. Nor has the morbidity reduction potential of a surveillance program been tested. These would be beneficial topics for study.

Therefore, it is easy to say why medical screening and early disease detection could be of benefit ---- decreased morbidity of chronic disease detected at more favorable treatment stage. It is much harder to say whether screening would actually accomplish this goal. It could, but it has not been tried.

Sincerely,

Alan M. Ducatman, M.D., M.Sc.
Professor of Medicine
Director, IOEH

enclosure
AMD/mk

Question from Senator Lieberman to Dr. Alan Ducatman, M.D., M.Sc., Director, Institute of Occupational and Environmental Health, University of West Virginia

Question 1:

In your opinion, what should an epidemiologic study of people who underwent this treatment cover and what federal agency should conduct such a study? How should such a study be structured? Should it cover veterans and civilians? Should it distinguish between individuals who were treated as children versus individuals who were treated as adults? Should it distinguish between men and women? What health problems should it cover? In your opinion, could the Submarine Survivors Group database provide the basis for such a study?

Question 2:

It is my understanding that although nasopharyngeal irradiation was used on thousands of people (one estimate is 400,000 people), today, many doctors are unaware that these treatments ever occurred. As a result, they do not ask their patients whether they underwent this treatment when they seek medical treatment for head and neck problems.

Dr. Ducatman, have you found that this is true? Do you know whether patients that have head or neck problems are commonly asked by their physicians whether they underwent nasopharyngeal irradiation? Can you explain why early notification may decrease the risk that these patients will become seriously ill?

Question 3: Intergenerational Effects

In your opinion, can the possible health effects of nasopharyngeal irradiation be passed on to successive generations?

Radium Experiment Assessment Project
Submarine Survivors Group

Jim Garrity ________
President

Stewart Farber, MSPH________
Vice President / Science Advisor

RADIUM NASOPHARYNGEAL IRRADIATION "TREATMENTS"

Invited Testimony presented at a hearing of the
U.S. Senate Committee on Environment and Public Works

Subcommittee on Clean Air and Nuclear Regulation
Washington, DC

August 29, 1994
(Rev. 1)

by

Stewart A. Farber

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My name is Stewart A. Farber. I am trained as a public health and environmental scientist having received an MS in Public Health (Air Pollution Control) from the University of Massachusetts School of Public Health ('73) following several years of professional work experience as an R&D Organic Chemist. I received an AB in Chemistry from Brown University ('67) and subsequently completed graduate medical coursework in genetics, biostatistics, and biochemistry at the University of Vermont College of Medicine.

During the past 20 years, my professional experience has focused on radiation risk assessment and improving radiation monitoring of the environment around fixed nuclear facilities and in designing and conducting high quality environmental, occupational, and emergency plan radiation exposure monitoring programs. This experience includes both staff technical and managerial support for a dozen nuclear power plants (as an Environmental Engineer, Assistant Environmental Lab Manager, Sr. Radiological Engineer, Assistant Nuclear Information Manager, and Operational Support Manager.) and independent consulting support to State Health Departments, consulting firms, utilities, manufacturers, law firms, towns, insurance companies, and most recently the *Submarine Survivors Group* related to radiation risk assessment, public health and environmental issues. My project management experience includes serving as the Project Manager for the design and startup of a centralized radiation monitoring lab serving 7 nuclear power plant sites. I served as Project Manager for the first fully functional computer based emergency assessment and response system brought into operation in the U.S. following the TMI accident, and as Project Manager for the design, installation, and calibration of a wide-range gaseous effluent radiation stack monitor for a 3 unit BWR power plant.

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For the past eight months, I have dedicated my efforts to prompting a long overdue governmental and medical response to what I consider a significant public health issue related to ionizing radiation exposure. Radium nasopharyngeal irradiation has in only a few months due to my joint volunteer efforts with Jim Garrity, with whom I joined in February in establishing the *Submarine Survivors Group*, emerged from the dustbin of medical history. The *Submarine Survivors Group* was formed to prompt honest and ethical evaluation of the neglected and forgotten history of radium nasal irradiation.. This issue has suddenly been recognized as a long forgotten medical "treatment" that clearly resulted in significant levels of beta and gamma radiation exposure to the nasopharynx and base of the brain of adults and children, including infants under 1 year of age. The level of exposure, the likely health risk to each exposed individual, and the collective dose and risk because of the size of the irradiated military and civilian cohort dwarfs all radiation exposure issues which have been publicized since Dec. 7, 1993 following Hazel O'Leary's press conference as part of recent DOE biomedical experimental concerns. In January 1994, the Clinton administration responded to the media and public focus on human radiation studies by establishing a task force composed of several cabinet officers, who in turn set up ethical and scientific standards working groups composed of top medical officials of the government. An Advisory Committee on Human Radiation Experiments was also set up with a charge to make recommendations and advise the government in several areas. The White House issued an Executive Order [#12891] on January requiring relevant agencies to review their records and identify any individuals who had been subjects for " human radiation experiments". As of early August, this human radiation experiment project had 187 people at work, and about $3.7 million had been spent with a completion cost estimated at about $24 million. The preceding is mentioned only because, the extensive and costly Human Radiation Interagency Working Group and the Human Radiation Advisory Committee have not turned up a single human radiation experiment that matches the scale, the potential impact on health, or the importance of the nasal radium irradiation issue. Were it not for the efforts of the *Submarine Survivors Group* this important issue would never have received the attention it warrants. Thousands of people who have come forward desiring to be part of an epidemiological study would never have had the chance to register and seek proper health screening and evaluation to address possible health problems connected to this "treatment".

Evolution of Issue- Background

In 1980 I became aware through two of my coworkers who received radium nasopharyngeal irradiation from a New London, CT based private physician of the existence of this radium 'treatment". My best friend, Mike Krabach received the "treatment" in 1966 as a recreational scuba diver while working for the General Dynamics, Electric Boat facility as a test engineer. Mr. Krabach was "treated" by Dr. Henry L. Haines, a former Navy Captain who I found through my literature search had developed the procedure for the U.S. Naval Medical Research Laboratory Submarine program during WW II as a young Navy Captain. In 1966, Mr. Krabach was referred to the private ENT practice of Dr. Haines by a supervisor at Electric Boat who mentioned Dr. Haines had a standard treatment involving radium irradiation of the adenoids for people having trouble equalizing pressure underwater. The second coworker received radium "treatments" as a child growing up in New London during the 1950s, also from Dr. Haines, for adenoid/middle ear problems (otitis media) common in young children for which radium nasal irradiation was being commonly used by Dr. Haines, and an estimated 1,000 to 2,000 physicians across the U.S, at that time.

These two coworkers had asked me as a radiation monitoring and health effects specialist to estimate what kind of doses had been delivered and what might be the long term risks to their health based on current scientific knowledge. In 1980, I initiated a limited literature search and quickly realized that this "treatment" was totally unlike any medical procedure with which I was familiar. Basic information about the nature of the procedure and the sealed radium source used (Monel metal encapsulated Nasopharyngeal Irradiator) was readily available in the medical literature of the late 1940s which allowed quick and approximate estimation of local doses . The radiation doses delivered on contact to the nasopharynx were in the thousands of Rem range. Doses at 1 cm depth in tissue were typically estimated at about 300 Rem from each source for a routine course of treatment (nasal irradiation was done bilaterally through each nostril) Contact doses of this magnitude were typically used in cancer therapy to treat malignancy, but I had been unaware up until that time of any common medical procedure performed for non-life threatending medical conditions on children or healthy adults involving radiation exposures at such a level.

As a radiation protection professional, I had devoted my career, and committed millions of dollars to ensure the capability to measure minute quantities of environmental radioactivity. I had developed analytical procedures and monitoring techniques to measure picoCuries (one millionth of a millionth of a Curie) and document radiation exposures to individuals of a few microRem (one millionth of a Rem) to a few milliRem (one thousondth of a Rem) from fixed nuclear facilities to meet standards of good practice and to meet Federal regulations. By contrast, the Radium nasal irradiation "treatment" involved the equivalent of putting a thinly encapsulated sealed one Curie Radium-226 source (one gram of pure Radium-226 in equilibrium with all its 'daughter' product radioactivity) up the nose of young children and adults for two to five minutes which delivered contact doses of kiloRem (2 to 5 **thousand** Rem).

It was quickly evident to me in reading some of the open medical literature (see Haines, HL, et. al., "Aerotitis media in Submariners", *Annals of Otology, Rhinology, and Laryngology,* Vol. 55, pp. 347-71, 1946) that this procedure became the treatment of choice from 1945 forward. The U.S. Navy, and Army Air Force standardized on radium irradiation after evaluating and eliminating various alternative Otitis Media treatments (topical nose drops - neosynephrine; various "psychological" treatments (chewing gum, listening to music, suggestion that trouble with pressure equalization would clear in a week, etc.) for any trainee who could not equalize pressure during escape tank training or hyperbaric (increased pressure) chamber exposure.

It was possible as of 1981 to estimate that a cohort numbering approximately 10,000 ex-Navy submariners received radium exposures to the nasopharynx (resulting in significant radiation exposure to the base of the brain) as a consequence of their initial training in Groton, Connecticut required for admission to the submarine service. This was based on a crude estimate of the fraction of trainees who had difficulty equalizing pressure (about 27 %) and the estimated number of submarine crewmembers trained during the 1950s alone during the large expansion of the U.S. Navy submarine fleet . All irradiations were administered from 1944 into the 1960s using a commercially available standardized monel metal irradiator (50 mg radium equivalent) and irradiation protocol developed by Dr. H. L. Haines and his Navy medical associates while Dr. Haines was serving as a Navy physician or subsequent to W.W.II while Dr. Haines was practicing in the New London, CT area as a private ENT specialist taking referrals from the Navy. Dr. Haines continued to serve as a key ENT consultant to the U.S. Navy up through his retirement in 1981.

The key question at that time related to this matter was what was presently known (or likely based on scientific knowledge) about the health impacts, if any, of radium nasal irradiation. I found out that what few publications on this specific "treatment" carried out as of 1980 were based on very short term follow-up (a few months to a few years) of small numbers of individuals and thus of no use. However, as a practicing Health Physicist a then current (1980) HHS Publication titled "Research Into the Biological Effects of Ionizing Radiation in the Bureau of Radiological Health", [HHS Publication (FDA) 80-8125] published by the U.S. Department of Health and Human Services, Public Health Service, Food and Drug Administration, Bureau of Radiological Health, July 1980 happened to cross my desk. This report contained a one page abstract of a current research project Titled: ***"Health Consequences of Nasopharyngeal Radium Exposure"*** being carried out at Johns Hopkins University, School of Public Health as a Ph.D. Thesis by a Dr. Dale Sandler.

Reproduced below from the above BRH July 1980 publication is what was and is **the only study ever done in this country about the health effects of radium nasal irradiation as it was carried out in the U.S.**

TITLE: Health Consequences of Nasopharyngeal Radium Exposure

DURATION: 1978-79

OBJECTIVE: To determine if irradiation of the head and neck for enlarged adenoids is associated with an increased incidence of benign and malignant neoplasia or other adverse health consequences

APPROACH: The study includes 2,925 children who attended clinics for hearing loss, including 904 who received radium treatment in 1943 through 1965. The patients were traced through 1079, and 90% were traced and sent questionnaires. Of the latter, 85% resulted in information regarding tumor status.

RESULTS: There was an overall statistically significant increase in benign and malignant tumors of the head and neck among the irradiated patients compared to the nonirradiated.. Although there were no thyroid tumors, there was a statistically significant increase in other thyroid diseases (a combination of hyperplasia, nodular goiter, and thyrotoxicosis) and of thyrotoxicosis alone. Of the 4 malignant tumors [added *Note:* these were deaths not cases] of the head and neck, 3 were brain tumors; there were no malignant tumors of the head and neck in the non-irradiated group. Although the radium treatment was intended to prevent hearing loss, more hearing loss was subsequently found in the irradiated that in the nonirradiated group.

IMPACT: The findings of the study will be part of the rationale used in the development of Agency decisions regarding risks. Study participants have been advised to have their hearing examined, and the irradiated patients have been advised to have their thyroid glands examined.

The above research abstract published not in the open literature but in a HHS BRH limited distribution publication allowed me to located a complete copy of the research report presented by Dale Sandler at a symposium sponsored by the FDA Bureau of Radiological Health on June 6-8, 1979 on this same research study.

The full unpublished (as of that time) paper titled; "Health Consequences of Nasopharyngeal Radium Exposure was presented at an FDA BRH technical symposium in 1979 is cited below [**Sandler**, D.P, Matanoski, G.M., Comstock, G.W., and Mitchell, T, "Health Consequences of Nasopharyngeal Radium Exposure", The Johns Hopkins University, School of Hygiene and Public Health, p. 15-24, appearing in "Symposium on Biological Effects, Imaging Techniques, and Dosimetry of Ionizing Radiations, held Rockville, MD, June 6-8, 1979, U.S. Dept. HHS, Public Health Service, Food and Drug Administration, Bureau of Radiological Health, HHS Publication (FDA) 80-8126, dated July **1980**]. This detailed preprint noted as **Sandler, 1980** was published in a BRH report two and a half years before its initial publication in a more condensed journal article. **Sandler, 1980** details a number of important results and conclusions which will be exactly quoted below as they were written:

Under RESULTS, **Sandler, 1980** notes:

On p. 20:

As can be seen from Table 5, there appears to be an excess risk of mortality from brain cancer in the exposed group which is significant with a p value of 0.01. This ratio may be of borderline significance since the exact confidence limits overlap one. There is a significant excess mortality from brain cancers in exposed individuals compared to U.S. populations and the confidence limits for this comparison do no overlap one. .....If we compare individuals who are followed through the cancer registry and through questionnaire for the incidence of tumors as shown in Table 6, the combined benign and malignant neoplasms of the head and neck occur twice as frequently in the exposed as compared to the nonexposed group and this excess is significantly different using either test. We have compared the incidence rates in the exposed to rates from the Connecticut tumor registry. Using these values, brain cancers and soft-palete cancers are significantly different in the exposed groups and both groups show a significant increase in malignant neoplasms with a twofold excess over that expected based on Connecticut rates....

The data regarding ear surgery and thyrotoxicosis (Table 8) indicated that the risks of these disorders were significantly higher in the exposed than non-exposed groups with relative risks of 2 and 9 respectively even after correction for several variables...

p. 22:

Because of its proximity to the radium applicator, the pituitary gland was exposed to the highest dosage of radiation, receiving 51 to 207 rads for a three-treatment course. It was felt that there might be hormonal changes associated with such an exposure which could be detected through the questionnaire.... There was, however, a remarkable difference in thyrotoxicosis observed among the exposed individuals.....In this case where the pituitary may be damaged or at least more heavily irradiated and the thyroid is functioning normally, there could also be an increased production [Note added: by the pituitary] of thyroid stimulating hormone (TSH) leading to diffuse thyroid hyperplasia. This could have caused the diagnosis of nontoxic nodular goiters and perhaps produced thyrotoxicosis. No other hormonal changes were noted on the questionnaire.

p. 23 SUMMARY

[Note: Reproduced in its entirety] : The results of the study of the chronic effects from irradiation of adenoids suggests a significant excess risk of head and neck cancers, especially brain tumors. The increased incidence of thyrotoxicosis in the exposed population may have resulted from hormonal imbalance secondary to pituitary gland irradiation and should receive further study.

Chronic hearing loss occurred more frequently in the irradiated group but it is difficult to be sure whether this indicated an ineffectiveness of the treatment or differences in the characteristics of the deafness in individuals selected for radium treatments.

p.24 DISCUSSION:

In summary, it is apparent that individuals who were exposed to radium treatments for enlarged adenoids have a twofold excess risk of head and neck tumors....Although separation of each of the tumor sites into individual categories of benign and

> *malignant did not provide for a significant excess for individual sites, the overall excess of all neoplasms, benign and malignant, of the head and neck is significant. The use of a combined group of lesions is probably a more meaningful method of analysis since all organs in the head and neck were exposed to some radiation and it may be chance or the presence of other associated risk factors which determine the exact site of the neoplasm.*

In January 1982, the "peer reviewed" paper was published in the **Journal of the National Cancer Institute**. See: (**Sandler**, D.P., Comstock, G.W, and Matanoski, G.M., "Neoplasms Following Childhood Radium Irradiation of the Nasopharynx, **Journal of the National Cancer Institute**, Vol. 68, pp. 3-8, **1982**). While the raw data reported was identical, this published JNCI ABSRACT has a completely different tone and emphasis from the SUMMARY published in Sander, 1980.

The **Sander, 1982** introductory ABSTRACT follows:

> *Eighteen to 35 years after admission to a clinic for the prevention of deafness, no increased overall cancer risk could be detected among 904 persons who had been treated with nasopharyngeal radium irradiation when compared with the risk among 2,021 persons who were either treated surgically or not treated at all, although there were differences at specific sites. An increased risk of developing both benign and malignant head and neck tumors was found among irradiated persons. Whereas no head and neck site showed a statistically significant excess, a slight increase of brain cancer occurred 15-20 years after radium treatment. No increase in thyroid cancer risk was observed, a result possibly attributable to the low radiation doses to this organ and the relatively small population irradiated.--JNCI 1982; 68;3-8.*

I have traced the evolution of the Summary and Abstracts of the various preprints and final published paper of the Johns Hopkins School of Public Health radium research because it highlights how the same research results can be stated in different ways that make it very difficult for even an informed reader to glean what is significant and what is not. One has to read three pages into the Sandler, 1982 paper, and read carefully to realized that it does finally state:

> *...there was a statistically significant overall excess of malignant neoplasms of the head and neck among exposed subjects. This excess was accounted for mainly by three brain tumor deaths for subjects exposed to radiation. The other malignant tumor was an undifferentiated anaplastic cancer of the soft palate. The RR of 1.6 for benign neoplasms of the head and neck was not statistically significant, but when combined with malignant neoplasms, the twofold increase in all head and neck neoplasms was statistically significant.*

The change in emphasis in the JNCI abstract assumes more significance as noted below related to what U.S. Navy reviewers responding to the radium issue misstated in their 1991 internal review report. Further, George W. Comstock, present director of the Johns Hopkins Training Center for Public Health Research in Hagerstown, MD was quoted in a recent AP news report (The Washington Post, June 9, 1994, "Researchers Check Possible Link of Radium Therapy to Cancer) as saying:

> *"There was a slight excess of head and neck cancers [added: in the 1982 Sandler study] but the numbers were not high enough to say this couldn't have occurred by chance"*

This statement is inaccurate vs. the results of the Sandler, 1982 study and misstates present knowledge about radium risks in 1994.

An ADDENDUM to the published Sandler, 1982(p. 8) paper notes that:

> *After completion of the survey, one malignant thyroid tumor was reported by an individual exposed to radiation. This indicates that a thyroid cancer risk might be demonstrated with longer follow-up. However, this could also reflect increased medical surveillance following notification of irradiation*

In 1981, having seen the Sandler, 1980 symposium presentation and after deriving the likely size of this Navy irradiated cohort, I quickly realized that this large group of irradiated submariners probably represented the best and most accessible cohort which existed in the world today to fill a scientific gap in understanding the dose-response relationship for effects of ionizing radiation exposure on the human brain. The submariners irradiated were not given anything like modern informed consent and full disclosure about the potential health risks of this radiation treatment at the time of treatment. I knew that even when questions were directed to Dr. Haines by some of the irradiation subjects in the late 1970's about radiation concerns, the irradiated subjects were provided inaccurate information in writing about the appropriate follow-up and health concerns. In 1981, I attempted unsuccessfully to interest epidemiologists at the Harvard School of Public Health in the need to pursue an epidemiological study of the Navy submariner cohort. At that time I was able to get the attention of a researcher from MIT (prior to meeting Dr. Ducatman) who was interested in trying to secure Federal funding for an epidemiological study of the Navy cohort I had identified. This researcher had worked with Dr. Robley Evans, Professor of Physics at MIT on the long-term radium "dial painter" research and I arranged a meeting in 1982 with Dr. Haines who had just retired from practice and reluctantly agreed to meet to discuss this issue. Dr. Haines in 1982 claimed all the Navy records on these submariner irradiations had been destroyed in a fire in St. Louis, and that he personally had unfortunately just sent all his private records to the dump "the week before" the 1982 meeting. As we now know , neither of these claims are accurate. The fire in St. Louis destroyed only a portion of DOD records and a physician in Connecticut is required to keep their records for at least 7 years after retiring before disposing of them.

At that time, no government or private research group involved in radiation epidemiology proved willing to pursue this issue and I put the matter aside since I was not well connected with the epidemiological research establishment and could not devote any more time to the issue. At various times throughout the 1980s I discussed this matter with various researchers on radiation health risks at places like Battelle Northwest's Hanford Environmental Health Foundation, but nothing came of it. In mid-1989, I met Dr. Alan Ducatman at a local meeting of the Health Physics Society in Massachusetts where he was giving a talk on conducting epidemiological studies of chemical health effects on Navy personnel. Dr. Ducatman at that time was Director, of

MIT's Environmental Medical Service. We spoke after the meeting about the Navy submariner radium issue and I sent Dr. Ducatman a number of papers and files I had on the issue. Dr. Ducatman in his presentation has reviewed some of his discussions at that time with me.

After reaching a number of dead ends in discussions with the Navy, Dr. Ducatman and I agreed to co-author a letter-to-the-editor of a respected medical journal to bring this issue to a broader medical and scientific audience. The letter-to-the-editor we co-authored in 1990 was submitted to the New England Journal of Medicine and provides the basic facts of the Navy submariner issue. After some delay due to it being shortened at the editors request and a longer delay waiting on a written response from the Dept. of the Navy, Bureau of Medicine and Surgery, published with the letter at the request of the NE Journal editors, the letter was published Jan. 2, 1992 in the New England Journal of Medicine (*Radium Exposure in U.S. Military Personnel, Vol. 326, No. 1, pp. 71-72*).

The Department of the Navy's response to the Jan. 2, 1992 letter, as published with the New England Journal letter does not dispute the existence of a cohort of at least the size claimed. As noted, the Navy spokesperson, Dr. Robert L. Bumgarner, M.D., Bureau of Medicine and Surgery, Department of the Navy makes a case that while it irradiated unspecified numbers of submariners, the risks were claimed to be "relatively small" and the Navy spokesperson maintained that:

> "Studies sufficiently large to allow discernment of associations of exposures and disease difficult because of very small excesses of disease. Identifying such small excesses would be almost as difficult as trying to determine any excess of deaths due to the chemical carcinogens in our diets."

The above letter-to-the-editor prompted limited local Connecticut press coverage in 1992 and the overall response of the medical and scientific community was totally underwhelming. The issue faded until 1994.

For a number of reasons, given the magnitude of the radiation doses delivered as reported in the NE Journal letter (which I calculated for the average of 4 ten-minute irradiations routinely administered by the Navy) and the unique nature of brain cancer (the most likely malignant outcome of this radiation exposure), the Navy's position appears insupportable and scientifically invalid. If a statistically valid epidemiological study cannot be done on a Navy submariner cohort which was conservatively estimated at that time to number no less than 5,000 subjects, exposed to local doses of 2,000 rads on average, it is doubtful that an epidemiological study of the effects of radiation on health could ever be carried out on any existing cohort of humans at reasonable cost with decent statistics and study sensitivity. Basically, if this potential submariner epidemiological study is as the Navy maintained in New England Journal of Medicine response too "difficult at best to complete" the Federal government is wasting its time and many millions if not potentially billions of U.S. tax dollars in trying to evaluate the effects of (and possibly compensate veterans and citizens for) environmental , occupational, or medical radiation exposure from existing , past, or planned governmental, industrial, or medical facility operations or practices.

A number of other references related to this matter are worth mentioning as noted below related to this issue. These include the following:

- A 1966 Medical Statement from Henry L. Haines, MD (and Drs. R. A. Loiacono, F. L. Dey, and R.A. Gaito) for Mr. Michael Krabach who received the Ra-226 irradiation procedure in 1966 as noted above. As noted, Mr. Krabach's 1966 billing statement shows that he was billed for Procedure D "Radium" carried out on 6/16/66, 7/6/66, 8/3/66, and 8/31/66. Mr. Krabach was advised that there was a simple treatment for this problem which the Navy submarine program had been using for decades. He was referred by a supervisor at Electric Boat to Dr. Haines who later formed **Ear, Nose, and Throat Associates of New London P.C.** at the address noted on the 1966 statement (464 Ocean Avenue, New London, CT). Note that the Statement lists Dr. Raymond A. Gaito as one of Dr. Haines' associates. Dr. Gaito joined this medical partnership in 1965, and is still practicing today in New London, CT. As of 1966, the "Radium" nasopharyngeal irradiation procedure was clearly still being done commonly enough by this group of ENT specialists to be listed on the medical billing statement (the form printed no later than 1965, since this was when Dr. Gaito joined the group) as one of the more common procedures performed by the practice.

- A note from Dr. Haines to M. Krabach which is undated related to the Ra-226 nasopharyngeal irradiation Mr. Krabach received in 1966. The recollection of Mr. Krabach is that this note was sent to him in the late 1970's after he called Dr. Haine's office with questions about the radiation doses he might have received in being administered the Ra-226 irradiation procedure in 1966. The note contains a number of substantial errors of fact and emphasis, including implying that the radiation dose "worked for less than a centimeter in all directions and only to the germinal centers of the lymphoid tissues with no effect on the older tissue." The depth distribution is more accurately noted in my 1/2/92 **New England Journal of Medicine** letter-to-the-editor. The correct reference to the procedure's developers is not Crowe-Barnum but Crowe, S.J. and Burnam, J.W (Recognition, Treatment and Prevention of Hearing Impairment in Children, Annals of Otology, Rhinology, and Laryngology Vol. 50:1-17, 1941). Dr. Haines is in error in stating: "There was no radiation to any of the other structures or to the thyroid.." Further, the statement that "This was not x-ray which has a tendency to splatter." has little if any physical or medical meaning. Dr. Haines also states: "No trouble has been seen with following of these cases, over 5000 of them through John (sic) Hopkins." is not correct.

- Johns Hopkins Hospitals issued a "PUBLIC SERVICE BULLETIN" dated Jan. 28, 1977 and an "ANNOUNCEMENT FOR PHYSICIANS also dated Jan. 28, 1977 which discusses the status of their concerns about the radiation therapy for adenoids procedure as of that date. Research was being carried out by Johns Hopkins scientists at that time which were raising flags about the issue of concerns related to "later development of malignant disease". As noted in the N.E. Journal of Medicine Letter of 1/2/92, the Sandler 1982 JNCI paper (and Sandler, 1980) had raised serious questions about combined benign and malignant cancers of the head and neck.

EARLY WARNINGS REGARDING NASOPHARYNGEAL IRRADIATION

An early review of the potential hazards of using Monel encapsulated radium applicators in the nasopharynx for the treatment of otologic conditions is found in a paper presented by Isadore

Lampe at a 1949 Symposium: Irradiation of Lymphoid Tissue (Presented at the Fifty-Fourth Annual Session of the American Academy of Ophthalmology and Otolaryngology, Oct. 9-14, 1949, Chicago, IL., and published as Lampe, I., "Potential Biologic Dangers of Nasopharyngeal Beta Irradiation", **Trans. Amer. Acad. of O & O.**, May-June 1950, p 505-507). This paper mentions that "over one thousand such applicators are in use currently in this country." Further, it mentions that other therapists (see Robbins, L.L., and Schulz, M, "Potential hazards from radiation treatment of hypertrophied lymphoid tissue in the nasopharynx", **Laryngoscope**, Vol. 59: p-147-155, Feb. 1949) had called attention to:

> *"The significant potentiality for producing radiation damage by beta irradiation of the nasopharynx and warned against its indiscriminate use. Their discussion is excellent and merits close attention."*

In summary, Lampe in 1950 stated that (see p. 507 of above reference):

> *"On the basis of the known biologic effect of beta radiation, the available data on the magnitude of the doses...which are currently used and the knowledge that the approved technic of repeated irradiations enhances radiation damage, the conclusion appears inescapable that permanent and significant radiation damage of the nasopharyngeal soft tissues is being produced not infrequently. This being the case, one can anticipate encountering an unpredictable incidence of the clinical manifestations of late radiation complications at some future time which may vary from a few to many years after treatment."*

Since the Department of the Navy carried out thousands of these Monel radium exposures to Submariner trainees during the 1950's (with some exposures of Navy and Electric Boat personnel as late as 1966) it is clear that the above published warnings in 1949 and 1950 by respected medical specialists in various medical journals were ignored. Further, as noted in the Dept. of the Navy response to my Jan. 2, 1992 Letter, the Navy still takes the position that it shouldn't be required to perform a study of this Navy cohort and that "a fruitful study would be difficult at best to complete.".

NEED FOR GOVERNMENT PRESSURE TO PERFORM AN EPIDEMIOLOGICAL STUDY OF' VETERAN AND CIVILIAN COHORTS

Since December 1993 when I began my efforts to focus attention on the need to perform an epidemiological study and outreach and identification program for the veterans treated with radium, information about the scope of this issue has grown tremendously. Subsequent to my first contacts with Sen. Lieberman staff in early January on the radium nasal irradiation issue, hundreds of news articles have been written nationally.The *Submarine Survivors Group* Hotline has received thousands of contacts from individuals exposed to radium nasal irradiation according to information provided by Jim Garrity.

At this time, a study of the veteran exposed Navy submariner and Army Air Force cohort is an absolute scientific/medical necessity. First it will determine if the head and neck and brain cancer observed in a much smaller cohort of children followed up by Johns Hopkins (see Sandler 1980 and Sandler, 1982) over shorter periods of time pertains to irradiated veterans. It will also provide valuable information about the effect of pituitary irradiation on thyroid function (thyrotoxicosis) that is simply not available via any other potential study group. The large population of irradiated veterans, which we now estimate numbers approximately 50,000 individuals must be notified of the need for follow-up health exams. An updated notice of potential health problems initiated by Johns Hopkins in 1977 is long overdue.

Secondly, studying the large population of exposed veterans will also help determine if the results noted by Sandler, et.al. regarding **no excess of thyroid cancer in children exposed** [when receiving nasopharyngeal radium treatments] **to between 11 and 14 rads** to the thyroid with the maximum being about 100 rads in small children is real or a statistical anomaly. Since many claims have been made that general environmental releases of radioiodine from various DOE defense facility operational releases (which have resulted in less that 14 rads thyroid exposure) may be responsible for thyroid cancers in adult members of the general population, a soundly designed study of nasopharyngeal radium irradiated Navy submariners health outcomes may also help the Federal government in evaluating claims of harm in the general population from widely dispersed fallout exposure from Hanford, Savannah River, and other Federal defense nuclear facilities.

BACKGROUND/FOLLOW-UP/RECENT DEVELOPMENTS

Even a summary of the recent press coverage of this issue would be too lengthy for the present forum. I will only review the News Release issued by the Submarine Survivors Group on 7/1/94. As noted in the 7/1/94 News Release, U.S. Government sponsored "human radiation experiments" involving 7,613 veterans (732 submariner and 6,881 Air Force trainees) who received nasal radium irradiation during 1944-46 are clearly documented in several medical journal reports published in the open literature by participating Navy and Army Air Force physicians found during my research of the literature. The radiation exposure delivered to the nasopharynx and base of the brain of these initial experimental military subjects and subsequently by the U.S. military to an estimated 40,000 servicemen and by more than 1,000 private physicians to no fewer than 200,000 members of the general public, mostly children, after this 'treatment' became a common clinical practice exceed the average radiation dose received to the base of the brain by the survivors of the Atomic bombing of Hiroshima and Nagasaki.

Further, based on the latest National Academy of Sciences risk factors [see App. 1 for details from BEIR-V Report] for radium nasopharyngeal irradiation as practiced in this country, the predicted health impact due to brain tumors alone from this procedure exceed the excess cancers from all causes observed among 79,856 A-bomb survivors studied to date. Based on the BEIR-V Report risk estimates citing a research report by The Johns Hopkins University, School of Public Health published in the Journal of the National Cancer Institute (Sandler, 1982), nasal radium irradiation is not just equivalent to a domestic Nagasaki up the nose of at least 250,000 Americans but actually is likely to exceed the excess cancer mortality from all causes seen among both the Hiroshima and Nagasaki A-bomb survivors.

Two published reports (Haines, 1946 and Annals of Otol., 1945, see **Bibliography** attached) document these initial experimental studies by the Navy and the Army Air Force using sealed radium applicators to shrink lymphoid tissue meet the definition of "human radiation experiments" as defined by Executive Order #12891 of January 18, 1994 establishing the Human Radiation Interagency Working Group". Since these two studies involved intentional irradiation of 7,613 adult submariner and aviator trainees sufficient to shrink lymphoid tissue after intense contact exposures to the nasopharynx averaging 2,000 Rad (see Farber, 1992) and had **not been classified as 'common and routine clinical practices...**involving incidental exposures to ionizing radiation' [per Executive Order #12891] as of the date these experiments were conducted, these irradiated veterans must be included among those human radiation experiments slated for in-depth review by the Human Radiation Interagency Working Group.

These two experiments, too limited in scope to prove the technique safe, were the basis for the Navy, and Air Force adopting radium nasal irradiation as a 'standard treatment' that we now estimate was subsequently used on more than 40,000 veterans.

Executive Order #12891 mandates that any "human radiation experiment" such as these initial radium irradiation experiments be reviewed by the Advisory Committee on Human Radiation Experiments to consider whether:

> *"..appropriate medical follow-up was conducted; and "if the experiments' design and administration met the ethical and scientific standards, including standards of informed consent that prevailed at the time of the experiments and that exist today."*

The experimental nature of the initial military radium nasal irradiations is proven beyond any doubt by a quote from Dr. Haines, who at the time was a Navy Captain at the Medical Research Department of the U.S. Submarine Base in Groton, CT researching problems with otitiis media in submariners. Navy Dr. Haines authored the paper "Aerotitis Media in Submariners" (see Haines, 1946) after completing his initial experiments using radium applicators. As Dr. Haines wrote (see **Haines, 1946,** p.368):

> *"The present study attempted to discover the causes and effects of aerotitis media and to find the best means of prediction, prevention, and treatment."*

Of 6,149 trainees evaluated 732 received a course (four ten minute irradiations on average, in each nostril) of radium irradiation. Navy Capt. Haines in his introduction to the cited report wrote:

> *"**Merely another clinical study would not meet the need.** In view of the fact that we had a **rich source of material,** and since every condition necessary for rigid **experimental** control was available, we felt it possible to meet rigorous **research** criteria, and thus to provide a fairly definitive study on the causes, effects, prediction, and treatment of the disorder. The present report describes aerotitis media as it appears in submariners, and recounts the **experiments** by which we attempted to understand it and mitigate its effects." [Note: added emphasis not in original] (see Haines, 1946, p.347)*

SUBMARINE SURVIVORS GROUP HOTLINE

To date thousands of veterans, dependents of veterans, and members of the public who received radium nasal irradiation from military doctors in the Navy or Army, have called the *Submarine Survivors Group* Hotline [(617) 471-5647] to register as having received radium nasal irradiation from 1944 to 1972according to Jim Garrity. These individuals who have registered with the *Submarine Survivors Group* and want to be part of an epidemiological study to assess long-term health effects of radium irradiation represent only a small part of the estimated 50,000 veterans and estimated 400,000 members of the public irradiated by more than 1,000 private physicians during the 1950s for ear problems who are now recognized as having received this "treatment".

NEED FOR FORMAL PROGRAM FOR IDENTIFICATION OF IRRADIATED VETERANS AND MEMBERS OF PUBLIC

As Dr. Ducatman and I wrote in 1992 in our joint 1992 Letter-to-the-Editor of the New England Journal of Medicine:

> *"The health outcomes of treated military personnel have not been studied. Surveys after similar treatment at a pediatric hearing loss clinic are not reassuring.... Military personnel have a right to know of their exposure; they may be at increased risk for head and neck neoplasms."*

A Department of the Navy spokesman, Dr. Robert Bumgarner, responded to the above New England Journal of Medicine letter published on 1/2/92 by Farber and Ducatman claiming that: "The risks incurred with these treatments were relatively small, despite the comments of Ducatman and Farber" . The Navy statement was based upon an internal report titled "Nasopharyngeal Irradiation with Radium: Its Use in U.S. Submariners and a Review of the Literature" dated June 6, 1991 authored by a Steven R. Warlick (See **Warlick, 1991** in Bibliography) which was I was able to obtain after Senator Lieberman(CT) and Senator Chafee (RI), former Secretary of the Navy intervened on my behalf. Unfortunately, this Navy report in large part misstates both the history of its use of radium irradiation and the likely health outcomes of the procedure. The cited Navy report (Warlick, 1991, p 4) states:

> *"He [Dr. Haines] discontinued the practice of nasopharyngeal irradiation in the early 1950's and sold his monel radium applicators to physicians at Yale University (personal communication with Dr. Haines, 1991)"*

However, Dr. Haines a key ENT consultant to the Navy throughout his long career continued to irradiate Navy personnel by referral into the 1960s, and members of the public as late as 1966. As noted earlier, my best friend and former coworker, received radium treatments by Dr. Haines in 1966. Obviously, Dr. Haines was less than accurate in his recollections when he communicated the above information to Navy investigators in 1991.

The 1991 Navy's Warlick (See Warlick, 1991, p 31) Report notes:

> *"Although an excess number of brain tumors was seen in the teated (sic) patients compared to the controls, the increase was not statistically significant"*

This Navy statement about The Johns Hopkins University (Sandler, 1982) study's conclusion is quite simply false. The Johns Hopkins paper published in the Journal of the National Cancer Institute (see Sandler , 1982, p 5) notes:

> *"..there was a statistically significant overall excess of malignant neoplasms of the head and neck among exposed subjects. This excess was accounted for mainly by three brain tumor deaths for subjects exposed to radiation. The other malignant tumor was an undifferentiated anaplastic cancer of the soft palate. The RR [Relative Risk] of 1.6 for benign neoplasms of the head and neck was not statistically significant, but when combined with malignant neoplasms, the two fold increase in head and neck neoplasms was statistically significant."*

The Navy has not accurately determined when it stopped using radium nasal irradiation on submariners because individuals who were involved were not accurate in their statements and recollections. The Navy has failed to honestly and ethically review the scientific literature about the likelihood of harm to veterans who received this 'treatment'. And since the 1991 Navy report was based on incorrect information and review of the scientific literature the Defense Department and Navy have callously failed to initiate an aggressive formal program for the identification and medical surveillance of the tens of thousands of veterans treated with radium nasal irradiation. It is time for the U.S. Government to recognize its obligations and act on this matter. The *Submarine Survivors Group* has for seven months been doing what many in the DOD have been saying could not be done. Calls to the *Submarine Survivors Group* Hotline have identified thousands of people who received this treatment according to Jim Garrity. A comprehensive and complete epidemiological study and outreach program is needed immediately to determine what are the real health impacts of this procedure and to ensure that affected individuals get proper medical treatment and attention. We are dealing with a domestic public health issue that likely exceeds the impact on health of Hiroshima and Nagasaki on the survivors in terms of cancer mortality and the time for evasive or inaccurate statements by responsible governmental bodies is past.

The fact that an issue of this importance could fall through the cracks of the system designed to protect U.S. public health and safety, indicts the process by which health risks are analyzed and responded to in this country. As a society, we are clearly not applying scientific knowledge in a consistent or sensible manner in regulating risks. Things need to change, and in regard to radium nasopharyngeal irradiation, a meaningful and comprehensive evaluation and follow-up needs to be initiated immediately.

It is clear solid data on the health outcome of this procedure is very much in the DOD's, DOE's, U.S. Government's, taxpayer's, and veteran's real best interests. The veterans have a right to know and good epidemiological data will help avoid a great deal of damaging psychological stress which many veterans may experience worrying about something which probably presents a health problem for only a small fraction of exposed individuals. The U. S. Government needs to know and to demonstrate it wants to do what is proper given all that is known at this time. Its been said that a little data disproves a lot of theory. Everyone's best interests are served by epidemiological study done on radium nasopharyngeal irradiation will have to be properly designed and executed to yield meaningful results. It took a comprehensive, methodical epidemiological study of more than 80,000 Hiroshima/Nagasaki survivors who were exposed to the direct radiation from an A-bomb to document a 5% increase in cancer mortality and a 1% increase in total mortality. A limited, improperly designed and or inadequately executed radium study will not yield information sufficient to the present need and would squander whatever moneys are spent in the study.

I also must note for the record that whatever is ultimately documented in studying the effects of radium nasal irradiation on health, the public can be assured that to my knowledge there is no current diagnostic x-ray, nuclear medicine, or therapeutic radiation based procedure that results in such elevated radiation exposures without full consideration of the risk vs. the benefit to the patient. An ill-advised past medical "treatment" like radium nasal 'treatments" should not influence the attitude of current health consumers regarding the need for an **indicated, properly performed** diagnostic or therapeutic radiation procedure. It has been said that fears of radiation have killed more people than radiation itself. An irrational fear of useful radiation based screening tests such as for breast cancer have been shown to result in women not being diagnosed with breast cancer early enough to treat the cancer successfully. Radiation treatment for cancer has also saved countless lives.

I would like to close with one bit of philosophy that I have used over the past eight months to motivate me to do what I have been doing on this issue.

> *It seems plain and self-evident, yet it needs to be said: The isolated knowledge obtained by a group of specialists in a narrow field has in itself no value whatsoever, but only in its synthesis with all the rest of knowledge and only insomuch as it really contributes in this synthesis toward answering the demand, "Who are we?"*
>
> -Erwin Schrodinger

Appendix I
Estimation of Radium Nasal Irradiation Health Effects

Dose Response Relationship Cited by BEIR-V Report

The fifth, and latest report prepared by the National Academy of Sciences, National Research Council's committee on the Biological Effects of Ionizing Radiation (BEIR) published in 1990 is titled "Health Effects of Exposure to Low Levels of Ionizing Radiation" (BEIR V Report). This series of reports has been prepared to advise the U.S. Government on the health consequences of radiation exposure. Congress in 1863 granted a charter to the National Academy of Sciences as a private, non-profit "society of distinguished scholars dedicated to the furtherance of science and technology and to their use for the general welfare." The Academy has a mandate that requires it to advise the federal government on scientific and technical matters. In preparing updated Reports on a given subject as the status of scientific knowledge advances with time, the BEIR Report series represents the best expert consensus standard of risk from ionizing radiation that exists at the time a report is issue.

In the section of the BEIR-V Report dealing with **Radiogenic Cancer at Specific Sites, Brain and Nervous System"** the BEIR committee cites and accepts as sufficiently 'powerful' for cancer risk estimation of the Brain and Nervous System only one epidemiological study (see **Sandler, 1982**, see Bibliography) of the health outcome of the typical radium nasal irradiation 'treatment'. This one study of the health outcome of using the monel metal radium nasopharyngeal applicator ("Crowe-Burnam technique) as developed and popularized by two Johns Hopkins University physicians) remains today the only basis to estimate potential health risk. Based on this study (**Sandler, 1982**) published in the **Journal of the National Cancer Institute**, a dose response relationship is stated by the committee for nasal irradiation:

As the BEIR-V committee report states (see **National Research Council, 1990, p 311**):

> **"Similarly, 3 of 904 patients treated with radium implants in the nasopharynx and followed for an average of 25 years after treatment were observed to develop brain tumors** *[Added note not in BEIR report: these were brain tumor deaths not cases]* **versus none in 2,021 controls; on the basis of an estimated average dose to the brain of 0.15 -0.4 Gy [15 Rem to 40 Rem] and an expectation of 0.57 brain tumors, the excess in this series has been calculated to range from 3.4 +/- 2.4 to 9.0 +/- 6.4 cases/10,000 PYGy for doses of 0.4 Gy and 0.15 Gy, respectively (Land, 1986)"**

While not immediately obvious, the above two BEIR-V committee stated factors for brain cancer risk are actually identical as noted below in factoring out the range of doses estimated by the BEIR committee for the typical course of radium nasal irradiation. It is not necessary to concern oneself with the dose delivered to an average individual receiving the radium nasal irradiation procedure, if one is only trying to calculate how many brain cancer deaths would be "predicted" based on the Sandler, 1982 study in following any given size group of individuals irradiated in a similar manner using radium nasal applicators. Factoring out the unnecessary (and somewhat confusing to the average reader) expression in this simplifying case for energy deposition or 'dose' [which is noted above in Gy (Gray), where 1 Gray = 1 J/kg (joule/kg) = 100 Rad)] simplifies the excess risk factor expression and allows simple calculation of how many 'excess' brain cancer deaths would be 'expected' in any cohort of radium irradiated individuals.

The conversion of the **BEIR-V cited 'excess' brain cancer** risk factor is noted below:

TABLE 2

BEIR-V Cited Risk Factor (p.311,BEIR-V)	Derived Simplified Equivalent Risk Factor
3.4 brain cancer deaths/10,000 PYGy per 0.4 Gy/treatment =	1'excess' brain cancer death per 7,400 PY of follow-up
9.0 brain cancer deaths/10,000 PYGy per 0.15 Gy/treatment =	1 'excess' brain cancer death per 7,400 PY of follow-up

The above BEIR-V cited risk factors both equate to **1 'excess' brain cancer death per 7,400 PY** Person-Years (PY) of follow-up if we are assessing the effect of an 'average' protocol (three 12 minute or four 10 minute nasal irradiations by a 50 mg monel irradiator) only on brain cancer excess risk.

Prediction Of Brain Cancer Excess Risk On A Cohort Of 79,856 Individuals Who Received Radium Nasal Irradiation Vs. All Excess Cancer Deaths Observed In Prior Studies Of An Identical Sized Cohort Of Hiroshima/Nagasaki Survivors

As a point of comparison, and to have some reasonable point of reference as to the significance of the health risk of nasal radium irradiation from brain cancer alone, we can calculate what would be predicted in terms of health effects (using the BEIR-V radium risk factor above for brain cancer deaths alone) if an epidemiological study of a randomly selected cohort of 79,856 individuals who received radium nasal irradiation (the same size cohort as that followed in the Life Span Study (LSS) of the Radiation Effects Research Foundation study of survivors of Hiroshima and Nagasaki summarized in Table 1, to Appendix I) were to be carried out.

As an aside, the **total radium nasal irradiated population** in the U.S. is estimated, based on present knowledge to **be no less than 240,000 individuals, or about 3 times larger than** the cohort followed by the Radiological Effects Research Foundation since 1950 following the health outcome of the survivors of the Atomic-bombing of **Hiroshima and Nagasaki**]

Thus, **if 79,856 radium nasal irradiated individuals** (P= 79,856) **were followed for 24.3 years (Y = 24.3) after receiving radium nasal irradiation** [the years of follow-up which are noted in the attached App. I, Table 1 for the LSS Hiroshima/Nagasaki study, which is essentially identical to the 25 years average follow-up in the Sandler, 1982 study of nasal irradiation] one would calculate the following number of **brain cancer deaths predicted** among these two equally sized cohorts based on the BEIR-V Committee's risk factor for radium nasal irradiation:

Table 3

Predicted Excess Brain Cancer Deaths (Group Size **P**; Followed for **Y** years) For Radium Nasopharyngeal Irradiation vs. Hirsohima/Nagasaki Survivor 'All Causes' Cancer Excess Follow-up

Excess Brain Cancer Deaths = [For **Radium Nasal Irradiated Individuals** of **Group size P**, followed for Y years each on average]	= (P) (Y) (BEIR-V Risk Factor) [where **P** = Number of persons = 79,856] [Y=Average Years of followup = 24.3] [BEIR-V Risk Factor = 1/7400] = (79,856)(24.3)(1/7,400) = = 262.2
Excess Cancer Deaths (All Causes) Observed Hiroshima/Nagasaki LSS Study (for same P & Y) - *[see Table 1, App. 1]*	= 250.3

As calculated above, the **predicted 262.2 excess brain cancer deaths** alone in a radium exposed cohort (based on the Excess risk factor as provided by the National Academy of Sciences) would exceed the **250.3 Excess Cancer Deaths from all cancer sites** noted in Table 1, Attached found in studying health outcomes **among the survivors of Hiroshima and Nagasaki**. of equal size and followed for the same duration. It is clear there are likely to be **many other likely health impacts** of radium nasal irradiation in this radium treated cohort based on the Sandler, 1982 study other than excess brain cancer. These include the observed 9 fold higher risk of thyrotoxicosis (hyperthyroidism due to enlarged thyroid, often referred to as Graves disease) noted in the Sandler, 1982 publication. The elevated rate of thyrotoxicosis due to radium nasal irradiation is suspected as being due to pituitary irradiation from the radium procedure sufficient to interfere with normal hormonal balance controlled by the pituitary and the hypothalmus interactions, which are the master glands of the human endocrine system.

The Sandler, 1982 study is admittedly only one study of 904 individuals who received radium nasal irradiation for whom the researchers attempted to determine health outcome after 25 years by looking at health statistics available . However, the health impacts suggested by this one study clearly can not be ignored. A larger, more comprehensive epidemiological study evaluating the health effects of radium nasopharyngeal irradiation on the health of the estimated 50,000 veterans population and on a representative cross section of the 200,000 members of the public who received this 'treatment' is clearly long overdue. This issue can no longer be ignored by the medical, public health, and governmental bodies that have responsibilities in these matters. The scientific/epidemiological data which currently exists as to level of risk to the health and well being of no fewer than 40,000 veterans of the Navy and Army Air Force and no fewer than 200,000 members of the U.S. general public by private physicians demands expanded evaluation and ethical follow-up immediately.

Final Note:

There is no leap of faith required of a reviewer related to understanding this risk 'estimate', nor is specialized training in biostatistics or radiation dosimetry. The BEIR-V committee cited radium nasal risk factor estimated a range of doses to the brain from the nasal irradiation procedure. However, as discussed above if we are comparing radium exposure health outcome in a larger cohort based on the observed health outcome in a smaller cohort who received the same radium treatment protocol, assumed average dose delivered to the brain is irrelevant.

The basic simplicity of the excess risk factor estimation is easily seen in that the Sandler, 1982 study found 3 brain cancer deaths in following 902 radium nasal irradiated individuals for health effects over a period of 25 years. As the BEIR-V report notes (p.311), 0.57 brain tumors would normally be 'expected' to be observed in a group of 902 individuals followed for 25 years based on average rates of brain cancer incidence in the U.S. population. The' Excess' risk of brain cancer deaths documented by the Sandler, 1982 study is the 'Observed'-'Expected' [(3 -0.57) = 2.43]or a net (uncorrected, and slightly simplified) 'Excess Risk' of 2 43 brain cancer deaths per 902 radium irradiated individuals followed for 25 years after irradiation on average. Similarly, by simple ratio vs. the Sandler, 1982 published findings, if the health outcome of a group 10 or 100 times larger than the 902 individuals studied by the Sandler, 1982 study (which does actually exist based on how common nasal irradiation became in the 1950s) were to be studied for an equivalent period of time after irradiation, the expected or predicted number of 'Excess' brain cancer deaths (based on present knowledge) would be:

Table 4

Assumed Size of Radium Exposed **Cohort (P)** to Be Followed	**'Excess' Brain Cancer** Deaths **Predicted** in Following Cohort P (for 25 years)
9,020	24.3
90,200	243

The BEIR-V cited Brain Cancer Excess Risk Factor used in the Table 3 above predicted an excess of 262.2 deaths should the health outcome be studied in 79,856 radium nasal irradiation subjects for an average of 24.3 years after irradiation, vs. 243 excess brain cancer cases in Table 4. The BEIR-V stated risk factor expression folded in a number of minor adjustments. However for present purposes, it is evident the level of risk of radium nasal irradiation brain cancer risk is essentially equal if not greater than the excess cancer risk (all sites) to an equivalent population of Hiroshima/Nagasaki survivors.

This comparison of risk in Table 3 did not hinge on any sudden realization of the significance of the Sandler, 1982 results by the BEIR-V committee in 1990. The risk documented by the Sandler, 1982 study have apparently been overlooked, ignored, or misrepresented by almost every group which has reviewed the study's conclusion since it was published, including the Department of the Navy, Bureau of Medicine and Surgery in mid-1991 when the Navy was drafting an official response to the Farber, 1992 letter published in the New England Journal of Medicine. This institutional denial cannot be allowed to continue since it flies in the face of present knowledge, and ignores the human needs of so many people.

Summary of Excess Cancer Deaths Documented in Hiroshima/Nagasaki Survivors

Estimated Number of Excess Cancer Deaths and Proportion to Specific Cancer Site
1950-1978 (LSS Extended Sample, Exposed, NOTE: P=79,856, Y= 24.3 years avg.)

Cancer Site *(Specified Cause)*	Excess cancer deaths (cases) *Cities COMBINED*	Excess cancer deaths (cases) Hiroshima	Excess cancer deaths (cases) Nagasaki	*COMBINED* Hiroshima and Nagasaki *Radiation Related Excess Deaths as a % of Total From Specified Cause*	*COMBINED* Hiroshima and Nagasaki *Total of All Deaths (Includes non radiation related) From Specified Cause*
Leukemia:	*90.6*	66.4	27.3	*50.3%*	180
All sites except leukemia:	*159.7*	135.2	27.3	*3.5%*	4576
TOTAL EXCESS CANCER DEATHS (Cases):	*250.3*	201.6	54.6	*5.3%*	4756
BREAKDOWN OF ABOVE "All Except Leukemia" EXCESS CANCER DEATHS (Cases):					
Esophagus	*8.4*	10.6	-2.2	*5.4%*	156
Stomach	*41.6*	31.6	10.3	*2.4%*	1754
Colon	*15.8*	14.1	1.9	*10.1%*	157
Other digestive	*24.2*	20.0	4.5	*4.1%*	595
Lung	*32.1*	26.0	7.3	*7.0%*	459
Breast (female)	*15.4*	12.9	2.8	*12.0%*	128
Urinary Tract	*7.9*	4.7	2.8	*7.6%*	104
Multiple Myeloma:	*5.8*	2.8	2.8	*29.0%*	20
Deaths From All Causes:	*23,502*	18,471	5,031		
Mean Dose (in Rad)	*27.2*	21.3	45.8		
Survivor Subjects Followed (P):	79,856	60,482	19,374		
Average person-years (Y):	24.27	24.27	24.27		

Above Table Abstracted from: Table IX, p.67, GANN Monograph on Cancer Research, 32, 1986
(Kato, H., "Cancer Mortality, Department of Epidemiology and Statistics, Radiation Effects Research Foundation)
Above summary based on Life Span Study [(LSS) Extended Sample, Exposed] of 79,856 atomic bomb survivors
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Questions from Senator Lieberman to Mr. Stewart Farber, M.S.P.H., Science Advisor, Submarine Survivors Group

Question 1:

As I understand it, you and Mr. Garrity have financed the operation of the Submarine Survivors Group out of your own pockets.

Could you give me an idea of the costs you personally have incurred to date? Have you or Mr. Garrity sought outside, private funding for operation of the Submarine Survivors Group? If so, what successes have you had?

Question 2:

In your opinion, what should an epidemiologic study of people who underwent this treatment cover and what federal agency should conduct such a study? How should such a study be structured? Should it cover veterans and civilians? Should it distinguish between individuals who were treated as children versus individuals who were treated as adults? Should it distinguish between men and women? What health problems should it cover? In your opinion, could the Submarine Survivors Group database provide the basis for such a study?

Question 3:

In your opinion, can the possible health effects of nasopharyngeal irradiation be passed on to successive generations?

Radium Experiment Assessment Project
Submarine Survivors Group

Jim Garrity _________
President

Stewart Farber, MSPH_________
Vice President / Science Advisor

September 27, 1994

Response to Questions posed (letter dated 9/12/94) by Senator Lieberman to Mr. Stewart Farber, MSPH, Science Advisor to the Submarine Survivors Group

Question 1:

The costs incurred by Stewart Farber related to prompting appropriate medical/scientific follow-up of radium nasopharyngeal irradiation predate the formation of the *Submarine Survivors Group* in March 1994 by an agreement between Mr. Farber and Mr. Garrity.

Mr. Farber has since December 1993 dedicated approximately 2,020 person-hours of work related to this effort and about $5,850 in out-of-pocket cash expenditures for phone, travel, office supplies, legal services, and postage. At a nominal discounted value for his services as a Consulting Scientist of $50 per hour of services performed (vs. a normal "consulting" rate of approximately $100 per hour) the above services value and cash expenditures equate to a cost of $106,850.

Mr Garrity has since February 1994 dedicated approximately 2,500 person-hours of work related to this effort and about $5,700 in out-of-pocket cash expenditures for phone. travel, office supplies, legal services, and postage. At a nominal discounted value for his services as a computer consultant of $30 per hour of services performed (vs. a normal "consulting" rate of approximately $60 per hour) the above services value and cash expenditures equate to a cost of $ 80,700.

The total of the above costs personally incurred to date for both Mr. Farber and Mr. Garrity total $187,550.

To date the *Submarine Survivors Group* has solicited funding or *pro bono* services to support its operations from private organizations and entities including the Veterans of Foreign Wars, the American Legion, the National Association of Atomic Veterans, the Cavallo Foundation, the Center for Defense Information, the City of Quincy (MA), Submariners, Inc., a partial small scale test mailing to individuals who registered with the *Submarine Survivors Group,* the law firms of Perkins, Smith & Cohen; Edwards & Angell, and Ropes & Gray. Proposals seeking foundation support are currently being prepared for submission to the Fund for Constitutional Government, the Stuart Mott Foundation, the Deer Creek Foundation, the W. Alton Jones Foundation, the Mary Reynolds Babcock Foundation, the Winslow Foundation the Schumann Foundation, and the Rockefeller Family Fund

To date approximately $1,500 in funds have been received from private parties and the National Association of Atomic Veterans. *Pro bono* legal services by the lawfirm of Perkins, Smith, &

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Cohen, Boston, MA valued at an estimated $7,000 have been pledged to help incorporate the group as a 501c(3) non profit corporation in the near term.

Question 2:

To properly evaluate the effects of radium nasopharyngeal irradiation on health it will be necessary to perform an epidemiological study on at least 3 separate cohorts. It is clearly necessary to distinguish between individuals treated as children vs. those treated as adults. Children who were treated by private physicians include both males and females and a study of children should include a large enough group to distinguish health outcome on both males and females. Young Adults treated by the Military include almost only males and should be studied by some mechanism involving or funded by the VA. Young Adults-females were also treated with radium in large numbers by private physicians in the 1950s during their training as flight attendants will need to be studied separately since certain possible effects of radium on the pituitary glands functioning involve hormonal control of bodily reproductive and female functioning unique to females.

In summary, the radium irradiated study cohorts required to be studied based on present knowledge include the following three groups:

1) Children (both males and females under 12)
2) Young Adults - Male (Submariners, Army Air Force trainees)
3) Young Adults - Females (Commercial flight attendants)

The basic components of an overall radium nasopharyngeal irradiation study program include the following:

- Outreach and Identification of (representative cross-section of) Various Potential Study Cohorts
- Epidemiological Study of Exposed Individuals in Each Cohort
- Medical Surveillance and Follow-Up of Affected Individuals

An Epidemiological Study will require the following steps:

- Document each individual's radiation exposure history

- Document each individual's medical/personal history

- Complete a detailed health condition survey form history. For any cancerous or precancerous lesions, secure pathologist's diagnostic codes.

- Develop detailed dosimetry for the Radium Chemical Corporation standard monel-metal radium nasal applicator used in vast majority of all radium nasal irradiation treatments. Secure a number o these existing sources and using current phantoms, TLDs, and exptrapolation chambers develop refined estimates of actual dosimetry in using these irradiators. Document dose to potentially affected structures in the head and neck including the base of brain, pituitary gland, hypothalmus, thyroid, eye, salivary glands, and nasopharynx.

- Develop a record of each exposed individual's major hospitalizations/medical treatments and family medical history. Secure for each individual authorization to obtain Medical/Service records which exist related to radium nasopharygeal irradiations received.

- Analyze both morbidity and mortality data obtained from epidemiological study and determine any suggested impacts on health including benign and malignant tumors and precancerous lesions of the head and neck (in sites such as brain including pituitary gland and hypothalmus, brain stem, cranial nerves, parotid and other salivary glands, nasopharynx, oropharynx, soft palate and thyroid gland) and any evidence of non-cancerous health impacts related to pituitary irradiation and hormonal upset. Related to hormonal upset assess any suggested dose response relationship for non-cancerous endpoints including effects of pituitary gland/hypothalmus irradiation. Potential effects may be noted in children with growth hormone, and in adults with effects on calcium metabolism (osteoporosis, unexplained breakage of teeth), thyroid-stimulating hormone (TSH) effects on thyroxine production vital to metabolism and general well being including psychological impacts (depression due to thyrotoxicosis), adrenocorticotrophic hormone (ACTH) effects on adrenal cortex functioning (allergies, autoimmune disorders such as rheumatoid arthritis, lupus, and Hashimoto's thyroiditis), luteinizing and follicle-stimulating hormones (LH and FSH) effects on estradiol secretion, oxytocin production, and ovarian follicle development in women (affecting fertility and miscarriage rates), stimulation of spermatogenesis in men (affecting fertility), and antidiuretic hormone(ADH) (affecting kidney function).

- Develop a record of each exposed individual's major hospitalizations/medical treatments and family medical history. Secure for each individual authorization to obtain Medical/Service records which exist related to radium nasopharygeal irradiations received.

At this time, it appears the database of radium nasopharyngeal irradiated individuals developed by the *Submarine Survivors Group*, numbering in excess of 100,000, is the most complete in existence. It will be necessary to expand the Outreach and Identification effort initiated by the *Submarine Survivors Group* to ensure that any cohort identified for epidemiological study is a representative cross-section of the irradiated population.

Information very recently provided to the *Submarine Survivors Group* has identified a complete, and unbiased (regarding the issue of "self-selection) cohort of over 15,000 Army Air Force personnel who received radium nasal irradiation treatments during the 1940s. This group of records once verified would provide a "non-self selected" cohort that could be studied in whole or in part as part of a comprehensive epidemiological study of young adult males.

Question 3

At present no scientific information available about the effects of ionizing radiation on health would suggest that health effects of nasopharyngeal irradiation could be passed on to successive generations. The radiation dose to the testis or ovaries of an individual receiving radium treatments would be quite small and based on present knowledge much too low to cause any measurable genetic risk.

However, there is a possibility that hormonal imbalance in the mother caused by nasopharyngeal irradiation could cause developmental problems while a fetus were in utero that could affect a child. The effects would be developmental and not necessarily genetic in origin. However, the child could suffer adverse health impacts, including cancer.

The potential mechanism is analogous to the problems seen with children exposed *in utero* to the drug Diethylstilbestrol (DES) use by a mother. DES mimics the natural estrogen hormone estradiol. Testicular and epidydymal abnormalities and an increase on oligospermia have been noted in male children exposed to DES *in utero* with resultant infertility. Similarly, DES exposed daughters have more difficulty conceiving and have an increased incidence of early abortion, ectopic pregnancy, and premature births With radium nasal irradiation, should there be a documented significant imbalance in various hormones in a mother including estradiol subsequent to receiving this treatment, it is possible health effects on a child may be noted long after the radium treatment is administered This effect could occur in children born to mothers who received radium irradiation prior to becoming pregnancy who become hormone imbalanced -- and not just while a fetus was *in utero.*

However, this mechanism of hormonal upset affecting children of irradiated individuals would require detailed study of the radium nasopharyngeal population to demonstrate. Such an effect has not to date been documented or suggested in studies of radiation exposure to the head and neck

STATEMENT OF:
Fran Kenneally
Waterford, Connecticut

PRESENTED TO:
United States Senate
Subcommittee on Clean Air and Nuclear Regulation
August 29, 1994

My name is Fran Kenneally. I am 47 years old and was born and raised in Waterford, Connecticut. When I was between the ages of 6 and 8 years old, my parents brought me to an ear, nose, and throat specialist Dr. Henry L. Haines in New London, Ct. He diagnosed that I had adenoid trouble. He was recommended by our family physician Dr. Dyer. At that time Dr. Haines was using the radium rods to treat the adenoids. I went to his office and he would put these rods up my nose. After about a year and a half of these treatments he finally removed my adenoids along with my tonsils. After this operation I started getting nosebleeds. I was taken to the hospital on several occasions and had my nose packed and cauterized at the emergency room. I also went to Dr. Haines office numerous times and had the cauterization performed there. After the first radium rod treatment, I remember that I was very frightened to go back. I know I went at least 8 to 10 times and the only solace I had was that I could lay there and read comic books. Sometimes I would have to lay down for the treatments while other times I could sit up. I can't remember the details too clearly because after all, I was just a child, and I despised the treatments immensely.

At 14 years of age I began having female problems consisting of irregular and painful menses and at the same time I was having excruciating headaches. I was brought to a gynecologist who said I had an infantile ovary and would more than likely always have female problems. These headaches were so intense that I would have to go to bed. My parents brought me to a neurosurgeon who did some testing for example, an EEG, an evoke response test, and sinus x-rays. I was sent to an ophthalmologist for my eyes. The neurosurgeon never could find out what these headaches were from. I was also sent to a dentist to determine if my teeth were causing the headaches. The dentist pulled four side teeth (two on each side of my front teeth) that were not decayed and replaced them with a partial plate. I continued to have the headaches. It was a couple of years before they subsided for no apparent reason. During that time I was given pain killers and the headache thing was pushed aside. The doctor said that maybe they (headaches) went along with the gynecological problems. I really don't recall if they went away or if I just got used to them. I seemed to have blocked out a lot of things during that time.

In 1966 I was married. I was still having these same female problems. I became pregnant and had my first miscarriage after carrying for six weeks. In December 1967 my son was born brain damaged. From the time I was 23 to 35 I had 5 more miscarriages. I never knew I was pregnant due to the late menses and constant lactation from my breasts. I went to different doctors to get opinions as to what was causing the miscarriages. I was referred to Dr. Burton L. Caldwell an endocrinologist in New Haven, Ct. for the first time around 1970. He did a blood test concentrating on the prolactin level in my blood stream. The prolactin level in a nursing mother is at a level of 25. My level at one time was over 300. He then began more testing including a CAT SCAN. When they initially started the test they found out that I was allergic to the dye so only part of the test was done. He did however; find a growth in the brain but could not see it clearly or define any of it's properties. Dr. Caldwell tried treating the tumor with a new drug called Bromocryptine to try and shrink it. I had an allergic reaction to this drug and went into anaphylactic shock. I was taken to the emergency room where I was treated for shock. I was then admitted to the hospital and my gynecologist Dr. Spitz who was working with Dr. Caldwell via the telephone was going to try to give me this same drug a quarter of a pill at a time. My body would not tolerate this drug. I was then sent to Massachusetts General Hospital for an evaluation. I had a new test called an MRI. (magnetic resonance imaging) The doctors could now see the tumor clearly. They discovered that I had a pituitary gland tumor. If I chose to have an operation to remove it they would have to leave a portion of it intact because of its location. Also it would increase in size and the portion removed would more than likely grow back after a period of time. They also told me that there was only a forty percent chance that everything would be fine after the operation. Having a handicapped child I chose to search for other options.

I left Massachusetts General Hospital and learned of a clinic at Yale New Haven Hospital that would take me. They wanted to experiment with drugs that were legal in Europe but not approved by the Federal Drug Administration in the United States. I decided to give it a try. I was monitored daily while taking these medications and as fate would have it I had to stop taking them. If I had continued taking them any longer I would have had irreparable damage to my liver and kidneys. My only options now were radiation treatments or the operation. I chose the radiation treatments. I had 25 cobalt treatments at Uncas on the Thames Hospital in Norwich, Ct. The doctors at this facility told me that it was very possible that I could have had this tumor since I was fourteen years old. Also during all that time the tumor would not allow the pituitary gland to work correctly. It would emit hormones when they weren't needed. I would faint from too much adrenalin and my heart would race because my thyroid was not working properly and there were many other pituitary related problems.

I am a single parent of a mentally handicapped son. He had problems dealing with my illness. His way with dealing with it was ignoring it. If I passed out he would step over me and pretend it was not happening. After a short time I had my friend Jeanne Brennan move in with us. She took me to each and everyone of my radiation treatments and was and continues to be of great help to my son and myself. Throughout all of my illnesses I continued to work a 40 hour week job until recently.

After the radiation treatments it was found out through the MRI results that the pituitary gland was burnt out as well as the thyroid gland from the cobalt treatments. I take synthetic hormone drugs to help with the absence of these glands daily and will continue to do so for the rest of my life. My body does not produce any estrogen (I can't take it synthetically.) I have osteoporosis and every three months for two weeks I take a drug called Didronel. Every six to eight months I have a bone scan which enables the doctor to see how brittle my bones are. The bones have continued to weaken steadily. Last year I had pneumonia and just from coughing I broke a back rib. I have many reactions to drugs (even aspirin) which makes it very difficult to treat my illnesses. I can only take one form of an antibiotic because I have had reactions to all others.

Late last year I read an article in my home-town paper (The Day) about Jim Garrity and the problems he has encountered after having the nasal radium treatments. This caused me to remember my own experience of the radium rod treatments. After contacting Dr. Caldwell to ask him if this treatment might have caused my problems, he said that there was not enough study or proof on this to say it did or did not cause these problems but to give Jim a call and find out more about it.

In the past few years my health has been declining. I just finished having a series of twelve compression casts on my right leg. I had an infection in my veins and arteries that none of my doctors could identify. They tried different drugs but I had allergic reactions to them. They did a biopsy on the right leg. The painful lumps then disappeared for a few days and reappeared on the left leg. Again they did a biopsy on the lumps in the left leg and they reappeared on the right leg.The doctor then decided to experiment with the compression casts. As a result the lumps have disappeared but I am left with a permanent scar, I wear prescription stockings, and walk with a cane. My chronic absenteeism from my job caused by almost daily doctor's appointments and illnesses resulted in many problems. One in particular was my supervisor and I had a dispute over my leaving for doctor's appointments. I had a TIA (mini-stroke) and was taken from work in an ambulance. I had to then have an operation on my head to check for temporal arteritis. The results came back negative and we still don't know what caused the TIA other than the stress of worriment. I had to apply for long term disability as well as Social Security Benefits. I am very disheartened because all of my life I have been very active.

In closing, I truly feel that the radium rod treatments I had as a child contributed to my past and present health problems. My internist Dr. Christopher Morren somewhat agrees. He's deducted a phenomenon in people like myself who received the radium rod treatments." It's an observation, not a proof, but in the back of the normal mouth you see nice normal pink tissue but with these patients in particular you see a web of white scar tissue in an "O" shape". It was quoted by Dr. Morren in an article that was done on me in "The Day" paper that he asks patients with this scar tissue if they had this radium rod treatment. "Until recently it was just sort of a phenomenon. But now we should actually take this into account in medical histories." Not one member of my family has had any of the sicknesses I have had. My maternal grandmother lived to be

98 years old. All the doctor's I have been to are totally baffled with me. Some doctor's have been truly frightened and hesitant to treat me because of my medical history. Thank you for your time and allowing me to share my experiences with you.

Submarine Survivors Group

Jim Garrity
President

Stewart Farber, MSPH
Science Advisor

RADIUM NASOPHARYNGEAL IRRADIATION "TREATMENTS"

Invited Testimony presented at a hearing of the
U.S. Senate Committee on Environment and Public Works

Subcommittee on Clean Air and Nuclear Regulation
Washington, DC

August 29, 1994

by

James J. Garrity, Jr.

President

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My name is James J. Garrity, Jr. and I am testifying today not only for myself but also the tens of thousands of military and civilian individuals who have contacted the *Submarine Survivors Group* Hotline. My personal experience with radium irradiation began in 1966 as a young man of eighteen attending Submarine School in New London, CT. In the first two weeks of this training all the "**Volunteers**" for Submarine duty were required to exit a pressurized chamber and ascend the Navy Training Tank (a 100 foot tall by 25 foot diameter cylinder of water) to simulate an escape from a disabled sub. While making the "free ascent" (no breathing apparatus was used) in the Training Tank, I was unable to equalize pressure from my middle ear. When I reached the surface, my head felt like it was in a vise and both ears were bleeding externally due to injury to my eardrums.

I was attended to by a Navy Corpsman who was at the surface of the Training Tank and was sent to the U.S. Naval Medical Research Laboratory in Groton, CT where I received a series of nasal radium irradiation "treatments" for the next two weeks. Upon completion of this course of radium "treatments" I was required to requalify in the escape Training Tank and did so with no problems.

I went on to serve in the U.S. Submarine Service and was honorably discharged in 1973. My health problems began to appear about ten years ago when I would lose my voice for long periods of time. I developed a chronic runny nose which worsened on eating. My teeth began to weaken and break for no apparent reason. After consulting with a number of doctors and dentists, not one could find anything organically wrong, and these doctors told me "it was all in my head". At this point, let me say what a helpless feeling it is when you know that there is something wrong and the medical profession cannot find anything specific, telling you it is "in your head". After hearing this many times, you start to believe it. In my case, I resigned myself to the fact I was going to feel lousy for the rest of my life and was not going to get any help.

At the beginning of February 1994, I read a feature article in a local paper about the radium treatments that were given to submariner and aviator trainees syndicated from the *Albuquerque Tribune* ("Radium went up the nose", Jan 28, 1994). This article noted that radium treatments were linked in a scientific study in 1982 to an excess risk of a variety of head and neck conditions. It was like my prayers were answered in that there might be a cause for my problems that if understood could help me in getting proper diagnosis and treatment. I called to get more information and a local paper sent a reporter to my home to discuss the radium treatments and my health status with me. The local *Quincy (MA) Patriot Ledger* ran a front page article a few days later about my treatments and the health effects I was experiencing. Almost immediately, I started to receive calls and letters from ex-military personnel and members of the general public who had received radium nasal irradiation, and were experiencing various adverse health effects which might be linked to radium irradiation "treatments". As more news articles were written and published, more calls and letters were received and a pattern started to emerge from these contacts. These people and I both needed help and some answers to our questions. It was not long before I was contacted by Stewart Farber who had been involved in researching this issue. We had a chance to meet and formed the *Submarine Survivors Group*. Since the start of our endeavor, we have used our own money and donated our time to research and collect data from thousands of individuals who have responded to the *Submarine Survivors Group* Hotline. The calls pouring in are telling my story and similar stories of brain cancer, thyroid disorders, acoustic and facial neuromas, and various conditions likely linked to radium irradiation time and time again. This "treatment" had almost no boundaries in that it was given to so many people both in the military and among the public who are now suffering aftereffects.

I personally answer the Hotline and read all the letters received. Some days I feel so helpless because the people who have contacted the *Submarine Survivors Group* need help and understanding. Stu Farber and I are only two individuals who are working to make sense of all this information. Some nights I work all night and still it is not enough. There are days I have to walk away from the phone to cry. The stories I am hearing of the death and disability in whole families is overwhelming. After starting the *Submarine Survivors Group* Hotline, I had to have the last of my teeth extracted. My dentist wanted me to have a physical and that is when I received a major dose of reality. My physician found a cancer in my nasopharynx and this quest took on a whole new meaning. At this point I could have quit what I was doing and felt sorry for myself, or I could do what I have done which is making a difference in many peoples lives.

When people call me I tell them to have a thorough physical by an ENT specialist or an endocrinologist if thyroid problems are present and tell them to discuss with their doctors what type of radium nasal irradiation "treatments" they received as a child or young adult in the military. I've received numerous calls from people that went to their physician on becoming concerned about radium nasal "treatments" after reading about and talking with the *Submarine Survivors Group* Hotline. Many of these people have subsequently been diagnosed with thyroid disorders, thyroid cancers, or other cancers of the head and neck that would have gone undiagnosed, and untreated if our efforts had not come to their attention. However, they often can be successfully treated and will live a relatively normal life. For other people it is not so easy. Their loved ones call or write that their father, or husband, or uncle died of brain cancer or suffer from thyroid disorder and cannot explain why. I feel helpless, but try to explain what may have happened. One of the first calls I got was from a lady in Quincy, MA who stated that her husband had died of a brain tumor. At the end of his disease, he treated her very badly. I tried in my own way to help her in following his Air Force health file, which she did not know how to read, which indicated that he had received radium "treatments" as an Air Force aviator and before his death he had simply lost his mind to the brain cancer. She cried on the phone and stated that I had given her husband back to her. When I got off the phone, I cried.

Gentlemen, we need help. Together we can make a difference. We can help the many thousands of people who got this treatment by getting them to see their doctors so that any problems can be detected early. We can also help explain some of the health conditions which affected people that have passed away, thereby increasing medical knowledge about the effects of radiation exposure on health.

Now is not the time to hold information back. Now is the time for action. We have a chance to make a difference in so many lives. Let's not pass up this unique and important opportunity. The *Submarine Survivors Group* is now cooperating with the U.S. Veterans Administration, Environmental Epidemiology Service to try and identify the veterans who received this treatment and will do the same with any other Federal or State agency that requests our help.

Thank you for this opportunity to testify today before the Subcommittee on Clean Air and Nuclear Regulation.

Statement of
Susan Mather, M.D., M.P.H.
Assistant Chief Medical Director for
Environmental Medicine and Public Health
Department of Veterans Affairs
Before the
Committee on Environment and Public Works
Subcommittee on Clean Air and Nuclear Regulation
August 29, 1994

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Mr. Chairman and members of the Subcommittee, I am pleased to be here today to participate in this hearing and to provide VA's testimony regarding the health effects of radium nasopharyngeal irradiation treatment. We share your concerns for the health and well-being of the veterans who received this kind of treatment during their service, as well as their families, and we very much appreciate your diligent efforts on their behalf.

VA's review including studies and plans for future studies

The use of radium nasopharyngeal irradiation for treatment of aerotitis media in military personnel was common in military facilities as well as non-military facilities during the 1940's and 1950's. The treatments were aimed at shrinking lymphoid tissues blocking the Eustachian tubes and thus helped prevent the occurrence of ear problems following pressure changes associated with submarine and flying duties. While the treatment has since been discontinued because of concerns about long-term health effects and new, alternatives for therapy, it was an accepted medical practice.

We have discussed the issue with both Department of Defense and Department of Health and Human Services officials and we have reviewed scientific publications related to the issue, including two large-scale controlled studies. A paper by Sandler et al., ("Neoplasms following childhood radium irradiation of the nasopharynx", Journal of the National Cancer Institute, 1982, 68:3-8) found no increased overall cancer risk but increased risk of developing benign and malignant head and neck tumors among exposed individuals. A paper by Verduijn et al., ("Mortality after nasopharyngeal radium irradiation for Eustachian tube dysfunction", Annals Otol Rhino Laryngol, 1989, 98:839-844) found no increase in mortality rates due to cancer. These studies indicate that questions remain regarding the possible cancer risks associated with this treatment.

As a result, VA's Office of Environmental Medicine and Public Health has been in contact with the Submarine Survivors Group and we have received the names of some submariners and airmen reported to have received radium treatments. VA employees are attempting to locate these veterans' military personnel and medical records to determine whether specific information relating to their radium treatments is documented. This will assist in determining the feasibility of a possible epidemiological study.

Documentation of the treatment of the subjects is essential for any valid epidemiological study to be done. If the treatment can be documented, we can then seek to identify an affected population through the examination of training rosters and submarine logs. A comparison group of people with similar characteristics but who did not receive radium treatments will also need to be identified. If two groups (exposed and controls) can be identified that are of adequate size to give statistically valid results, then morbidity and mortality studies can be designed, peer-reviewed, and carried out. A mortality study probably would be the first study to be considered. The suspected health outcomes of concern from previous studies are cancers and most of the head and neck cancers (with the exception of thyroid malignancies) are eventually fatal. Also, the time period which has elapsed is sufficient for radiogenic cancers to have been manifested. Finally, a mortality study can be completed sooner and is generally less costly than a morbidity study. If the mortality study suggests any other health effects related to radium treatments, a morbidity study can be designed to further evaluate those health effects.

VA actions to provide information and guidance to veterans

Initially veterans benefits counselors staffing VA's toll-free radiation help line and VA's general benefits information telephone service line may not have been fully advised about the concerns of submariners and airmen and the specific issues surrounding nasopharyngeal irradiation. However, this situation was corrected last spring, and information about how affected veterans can apply for disability benefits and VA medical treatment has now been disseminated nationwide.

More generally, whenever a veteran alleges involvement in experimental medical treatment during military service, identifying information such as the veterans name, claim number, dates of service, and exposure/experimentation information are taken by veterans benefits counselors and forwarded to the Department of Defense for tracking and further follow-up. Veterans benefits counselors assist veterans in filing claims for service-connected compensation, medical treatment, and other services. When appropriate, the veterans benefits counselors also provide additional information related to military treatment to the involved military service office. VA is committed to assisting any veteran who believes he or she may have been injured: by exposure to ionizing radiation; by any experimental medical care involving radiation; or by any other examination or treatment, such as nasopharyngeal irradiation.

Status of VA's radiation help line and other referrals and contacts

Of the over 1,500 reports of calls referred to the Veterans Health Administration (VHA) radiation database to date, only seven specifically mentioned these radium treatments.

Since January 1994 VA's radiation help line has referred to the Department of Defense 520 cases where veterans allege that they have undergone experimental or other treatment where they may have been exposed to hazardous material during military service. Although separate statistics have not been maintained on cases involving nasopharyngeal irradiation, the number is believed to be minimal, similar to VHA's experience.

That concludes my statement Mr. Chairman. I would be pleased to answer any questions that you or other members of the Subcommittee have.

HONORABLE JOSEPH I. LIEBERMAN, CHAIRMAN
SUBCOMMITTEE ON CLEAN AIR AND NUCLEAR REGULATION
COMMITTEE ON ENVIRONMENT AND PUBLIC WORKS

QUESTIONS SUBMITTED FOR THE RECORD
DEPARTMENT OF VETERANS AFFAIRS

HEARING ON
POTENTIAL HEALTH EFFECTS OF NASOPHARYNGEAL IRRADIATION

AUGUST 29, 1994

Question 1: In your opinion, what should an epidemiologic study of people who underwent nasopharyngeal irradiation treatment cover? How should such a study be structured? What health problems should it cover? In your opinion, could the Submarine Survivors Group database provide the basis for such a study? Do you envision further cooperation between the VA and the Submarine Survivors Group in the future?

Answer: Please refer to the document prepared by the VA Environmental Epidemiology Service (EES) titled "Feasibility of an Epidemiologic Study of a Cohort of Submariners who Received Radium Irradiation Treatment" (attached) in which the objectives and study design are discussed. The suspected health outcomes of greatest concern would be cancers resulting from the irradiation of the nasopharyngeal areas. Most head and neck cancers are fatal, and the risks could be evaluated with a mortality follow-up study. To evaluate the risks for some cancers, thyroid disorders, and other non-fatal medical conditions resulting from treatment, a more extensive and costly study must be undertaken.

As indicated in the report, the database compiled by the Submariners Survivors Association is a self-selected group of exposed individuals concerned about their health problems. The biases associated with this database would not make it an appropriate source of exposed individuals. However, it may, in the later stages of an epidemiologic study, provide information for follow-up purposes on those veterans included in the study. EES has established an excellent channel of communication with the Submariners Survivors Association and anticipates a strong involvement and cooperation with them in the future. Mr. Garrity has invaluable knowledge regarding the details of the radium treatments and the experience of the submariners, and he has been most cooperative with VA.

Question 2: You mentioned in your testimony before the Subcommittee that the VA has begun a feasibility study to determine whether an epidemiologic study will be feasible in the future. How is the feasibility study structured? What must it show before an epidemiologic study can begin? Once the feasibility study is complete, how long will it be before initiation of the epidemiologic study?

Answer: The first step of the feasibility study involves the review of the military records of a sample of 23 submariners and airmen identified from Mr. Garrity's database as service personnel who received the radium treatments. Military and medical records of this sample are being searched for documented evidence of the self-reported treatments. The National Personnel Records Center (NPRC) requested that EES submit release forms signed by the veterans before medical record files could be examined. Mr. Garrity has been assisting EES in getting those release forms sent to the veterans. As soon as EES receives the signed releases, NPRC can begin this review. It is important to have some source of independent verification of the radium treatments beyond the veterans' statement. If there is not sufficient evidence in the military/medical records to provide this information, a different approach must be taken. A study design similar to those utilized with Vietnam veterans and Agent Orange exposure known as a "Vietnam experience study" would have to be considered. This would compare health outcome of submariners identified from ship rosters, of whom 20%-30% of those serving in the 1940's and 1950's are believed to have been treated, with other Naval personnel unlikely to have received radium treatments. This type of study requires larger numbers of study participants in order to detect differences in health risks than the retrospective health study in which individual exposures can be identified.

Any of these full epidemiologic studies could be initiated by EES as soon as suitable funding sources can be identified. It is estimated that a mortality follow-up study would take 18 to 24 months to complete.

Question 3: As you know, both veterans and civilians underwent nasopharyngeal irradiation. An epidemiologic study, therefore, could cover both veterans and civilians. Has the VA ever conducted epidemiological studies in conjunction with the CDC? If so, have such cooperative efforts been successful? Would the VA support conducting a joint epidemiological study with the CDC which would cover both veterans and civilians who underwent nasopharyngeal irradiation?

Answer: In the 1980's, the VA contracted to CDC for the conduct of specific studies involving Vietnam veterans and Agent Orange exposure. However, the two organizations have never worked jointly on a study, and it does not seem practical to conduct such a combined study of civilians and veterans who received radium treatments. The VA EES research staff has had considerable experience in conducting follow-up studies of veteran populations and in the utilization of the variety of databases maintained by VA that can facilitate such studies. It would, however, be appropriate to coordinate the design of the two separate studies such that results could be easily compared.

Question 4: Secretary Brown, in an April 28, 1994 letter, stated: "Any veterans who believes that he or she has an illness possibly related to radium exposure during military service may contact the most convenient VA medical center or regional office for information on applying for medical care and/or initiating a compensation claim."

Under current law, what must a veteran who underwent nasopharyngeal irradiation establish in order to receive examination and treatment at a VA medical center? If a veteran has not yet been awarded benefits but he or she believes that he or she may have a disability related to military service, possibly deriving from nasopharyngeal irradiation, would he or she be eligible for VA treatment without regard to income level? Consistent with Secretary Brown's letter of April, my understanding is "yes."

Are VA medical benefits available to military dependents who were treated on base or who were referred by military physicians for this treatment to civilian physicians? If so, what must they establish in order to obtain treatment under current law?

Answer: In order to be eligible for VA medical care, all veterans must establish they were honorably discharged from active military duty for the minimum period specified by law. A veteran would present to VA staff a copy of his/her military discharge form, DD 214, identifying his or her condition of discharge.

Nasopharyngeal irradiation treatment does not qualify veterans, without special eligibility, for cost-free medical care based on such an exposure; therefore, the veteran's income level would be considered. Veterans exposed while serving on active duty to ionizing radiation from the detonation of a nuclear device in connection with the veteran's participation in the test of such a device or with the American occupation of Hiroshima and Nagasaki, Japan are eligible for cost-free VA medical care regardless of income level.

However, any veteran who feels they may have a disability possibly related to military service should apply for a disability examination through their nearest VA Regional Office. When awarded a service-connected disability for a condition, the veteran would be eligible for VA medical care for that condition without regard to income level.

The primary mission of the Veterans Health Administration, by law, is to provide treatment to veterans who have earned their entitlement to this care through active military service. Non-veterans are generally not entitled to care in VA facilities.

The Civilian Health and Medical Program of VA (CHAMPVA) allows VA to furnish treatment and medications to certain spouses and children of veterans who meet one of the following criteria:

a. the spouse and children of a veteran who has a total disability, permanent in nature, resulting from a service-connected disability;

b. the surviving spouse and children of a veteran who died on active duty;

c. the surviving spouse and children of a veteran whose death was the result of a service-connected disability.

Under CHAMPVA, VA normally pays a portion of the cost of treatment provided in non-VA facilities, although in some cases VA medical facilities are used.

Question 5: Must there be a manifestation of an injury before veterans who underwent nasopharyngeal irradiation can be examined and/or treated at VA hospitals? For example, if a veteran underwent the treatment but does not currently suffer from medical problems, can he or she obtain preventative or diagnostic treatment from the VA? If so, what must he or she establish to receive treatment?

Answer: Veterans who are seeking treatment for nonservice-connected disabilities, and who are not entitled to continuous outpatient treatment by specific laws, may be provided treatment and medications on an outpatient basis for a brief period if they are scheduled for a VA hospital admission. They may also receive this care if treatment will make hospital admission unnecessary, or it completes an episode of VA hospital care. If treatment is provided in these latter instances, the veteran must be released from care and referred to a private physician once the condition stabilizes. There is no special authority allowing for the treatment of veterans based on their undergoing nasopharyngeal irradiation.

Any veteran seeking VA medical care should apply for care at the nearest VA medical facility. Under current law, VA medical care shall be provided to service-connected veterans and to lower income veterans. Those nonservice-connected veterans with higher incomes may be provided VA medical care on a space and resource available basis and will be charged a co-payment for their care.

Question 6: Have VA physicians or VA hospitals been notified of the treatment's potential health effects and the possibility that treated veterans and/or veterans' dependents may be seeking treatment? If not, how does the VA propose to notify VA physicians and VA hospitals so that veterans and their dependents, who underwent the treatment, can be notified of the treatment's potential health effects? How should VA's notification efforts be monitored to ensure that they are successful? Please specify what steps the VA is taking or will take to effect such notification.

Answer: Because of the unresolved medical questions regarding possible adverse health effects resulting from radium treatments and VA's limited authority to provide medical surveillance and periodic health examinations to veterans without special eligibility for outpatient care as described in the responses to questions 4 and 5, the VA Central Office has not yet undertaken any actions to specifically notify VA medical centers, physicians, or the veteran population about this issue. (As stated in the answer to the third portion of question 4, the VA has only very limited authority to provide medical care to dependents of veterans.)

After consensus has been reached among the major responsible agencies with respect to the likely risks and recommended surveillance and diagnostic measures, this information will be disseminated to VA professional staff. At that time there will also be consideration of steps to disseminate such information to veterans.

Additional epidemiological research is likely to be needed before any firm conclusions and recommendations can be formulated.

Attachment

FEASIBILITY OF AN EPIDEMIOLOGIC STUDY OF A COHORT OF SUBMARINERS WHO RECEIVED RADIUM IRRADIATION TREATMENT

In a retrospective cohort study, also called a historical cohort study, a cohort of individuals is identified based on characteristics of exposure in the past and their subsequent disease experience is evaluated to a defined point in time. A cohort is identified solely based on the exposure status independent of disease status. The cohort selected for this study must be one in which a large number of individuals have been irradiated with radium. Also, reasonably reliable data on exposure of individual cohort members should be available.

The roster of 15,000 submariners who allegedly received the radium treatment is a roster of a self-selected group, most of whom have health problems (personal communication with Mr. James Garrity, Submarine Survivors Association). This group of veterans may not be appropriate for a cohort study for several reasons. First, they may or may not represent the entire group of veterans who received the radium treatments in the 40's and 50's. Second, they are self-selected into the group because of their health problems. Therefore, a study of this group of veterans will likely to be biased toward an overestimate of specific health risks. Third, because people with more serious health problems would have died already, a study of the survivors could underestimate the true risk. An alternative approach to study veterans who were treated with radium is discussed below.

I. Identification of Study Subjects

As a way of evaluating the feasibility of identifying a large number of Navy veterans who have received irradiation treatment with radium in the military during the 1940's and 50's and a group of controls, the following procedures are proposed:

1. Selection of a study group

1) Obtain a dozen names and social security numbers (or service numbers) of Navy veterans who contacted the Submarine Survivors Group, Inc.;

2) Request their military personnel records and medical records from the National Personnel Records Center;

3) Review their records for evidence of radium irradiation treatments;

4) For those veterans with documented evidence of treatment, search for their class roster at the New London US Naval Submarine Base;

5) If the class roster is not available, look for the name of the submarine to which he was assigned subsequent to his training;

6) Obtain microfilmed ship log of selected submarines from the Bureau of Naval Personnel;

7) List all submariners by their names, service numbers, and rank;

8) Search their records at NPRC for evidence of radium treatment;

9) Calculate the proportion of submariners with documented exposure history (to be used in the sample size estimate); and

10) Repeat the above steps until the desired number of individuals is accumulated.

2. Selection of a comparison group

Because of a "healthy veteran effect", the general US male population is not an ideal comparison group. Veterans, on the average, are healthier than the general population for several reasons including pre-induction physical screening, requirements to maintain certain physical standards, lifestyle changes that are conducive to better health, and better access to medical care. Therefore, a veteran group that was susceptible to the same selective factors as the study group would be an appropriate comparison group. Another group of submariners who were on active duty during the same period but did not receive the radium treatment will be an ideal comparison group. However, it is possible that some submariners received the treatment without the event being recorded in his military records. Because of this possibility of misclassification of individuals, other submariners are not suitable as controls. The next group of choice would be a group of sailors who served on surface ships during the 1940's and 1950's. Navy ships that were active during this period can be identified and ship logs of these vessels can be obtained from the Bureau of Naval Personnel. Names, service numbers and ranks of an appropriate number of sailors could be abstracted. As an additional means of guarding against misclassification (false negative) on exposure, their records can be searched at the NPRC for evidence of receiving the radium treatment and their names can be matched against the roster maintained by the Submarine Survivors Group.

II. Study Design Consideration

These two groups (exposed and control) can be studied for morbidity and mortality outcomes. A mortality follow-up study may be the most appropriate study design for several reasons. The suspected health outcomes of concern are cancers resulting from the radiation of nasopharyngeal areas with radium, and most of the cancers of the head and neck areas are eventually fatal. Also, at least three decades have elapsed since the treatment, a period which is considered sufficient for the manifestation and radiogenic cancer. Finally, a mortality study can be completed quicker and is generally less costly than a morbidity study. If the mortality study results suggest any health effects related to the radium treatments, a morbidity study can be designed to further evaluate the adverse health outcomes.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Disease Control
and Prevention (CDC)
Atlanta GA

TESTIMONY OF

JAMES M. SMITH, PH.D.
CENTERS FOR DISEASE CONTROL AND PREVENTION
PUBLIC HEALTH SERVICE

BEFORE THE

SENATE SUBCOMMITTEE ON CLEAN AIR AND NUCLEAR REGULATION,
SENATE COMMITTEE ON ENVIRONMENT AND PUBLIC WORKS

AUGUST 29, 1994

I am Dr. James Smith, Chief of the Radiation Studies Branch, National Center for Environmental Health, Centers for Disease Control and Prevention (CDC). Accompanying me is Dr. Dale Sandler from the National Institute for Environmental Health Sciences. CDC is pleased to have this opportunity to discuss the potential health effects of nasopharyngeal radium irradiation treatments and the possibility of undertaking new studies.

CDC has recently compiled current and historical literature relating to nasopharyngeal radium irradiation, which was an accepted medical treatment in the past. Most of the reports in the medical literature are about its use in children and military personnel. Nasopharyngeal radium irradiation was developed in response to observations that enlarged lymphoid tissue was present in a large percentage of children with middle ear hearing loss. The goal of the treatment was to reduce swelling of enlarged lymphoid tissue in the nasopharynx, which was thought to cause various problems including conductive hearing loss and aerotitis media[1]. The typical treatment was performed using two radium applicators, each containing 50 mg. of radioactive radium. After a local anesthetic was applied, the applicators were inserted through each nostril, placed near the opening of the eustachian tube, and left in place for approximately 10 minutes. Medical research on the treatment began in the 1920s. Following publication of several reports in the late 1930s and early 1940s, nasopharyngeal radium irradiation became fairly widely used in the civilian population. Its use was reported in Birmingham Alabama, Baltimore Maryland, Boston Massachusetts, Detroit Michigan, Vicksburg Mississippi, New York City, Cleveland Ohio, and Pittsburgh Pennsylvania. The use of nasopharyngeal radium irradiation by general practitioners and pediatricians, as well as otolaryngologists (ear, nose and throat specialists) and radiologists, was reported in the medical literature. Radium treatment was also used by the Army and Navy during World War II for treating aerotitis media. A symposium on its use and the underlying pathology was held by the American Academy of Ophthalmology and Otolaryngology in 1949. The use of nasopharyngeal radium continued into the 1950s, but was discontinued during the 1960s due to concern among physicians about the possibility of malignancy and because of the availability of alternative treatments, such as antibiotics and tympanotomy tubes (plastic ventilation tubes inserted through the ear drum).

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[1] Aerotitis media: a group of symptoms produced by the difference between the atmospheric pressure of the environment and the air pressure in the middle ear.

Military use of nasopharyngeal radium irradiation treatment began in World War II. Due to the rapid increase in military activity, aerotitis media rapidly became a problem for both the Army Air Forces and the Navy submarine crews, causing large numbers of divers and flyers to miss missions. Military physicians believed aerotitis was caused by enlarged lymphoid tissue blocking the eustachian tube and preventing equalization of pressure during descent, leading to the complications of aerotitis (pain, fluid in the middle ear, bleeding, and rupture of the drum). Because radium treatments shrank the lymphoid tissue, it was thought to be an appropriate treatment for this condition. Flyers with aerotitis missed approximately a third of their combat duty time. Thirty percent of men undergoing submarine training developed objective signs of aerotitis. Reports cited the return of personnel to their missions following treatment with nasopharyngeal radium irradiation. It is not documented in the medical literature when or why the military stopped using nasopharyngeal radium irradiation.

At the time nasopharyngeal radium irradiation treatments began to be used, many physicians believed that conductive hearing loss was due to blockage of the eustachian tube by enlarged lymphoid tissue. It was thought best to treat this form of hearing loss in childhood, before the loss became irreversible. Nasopharyngeal radium treatments also were advocated to prevent repeated viral and bacterial infections, for asthma which occurred with repeated viral infections, for recurrent middle ear infections, for sinusitis, and for recurrent tonsillitis.

Early proponents of nasopharyngeal radium irradiation therapy cited several reasons for the advantage of nasopharyngeal irradiation over surgery and conventional X-irradiation. Radium treatment could shrink lymphoid tissues in areas that were inaccessible to surgeons. Compared with surgery, the radium treatment did not require general anesthesia and could be done as an outpatient procedure. In the military, radium applicators were more portable than conventional x-ray equipment, and therefore radium was the only radiation treatment suitable for treatments in the field during war. It was thought to be safer than conventional X-ray treatment, because the radiation could be more accurately applied to the area of interest and did not have to pass through skin, soft tissue, and bone.

In summary, nasopharyngeal radium irradiation was an accepted medical treatment for hearing loss, aerotitis media, and other middle ear problems in the 1940s and 1950s. It appears to have been used mostly for military personnel and civilian children. It was used by pediatricians and general practitioners as well as ear, nose and throat specialists and radiologists. Nasopharyngeal radium irradiation was believed to be safer than conventional X-ray treatments, and to be useful in situations where surgery was not available.

Concerns about the safety of nasopharyngeal radium therapy began in the late 1940s. Initial concerns were about ulcerations and keratoses (horny projections from the tonsils and nasopharynx) which may require plastic surgery, particularly when they occur in areas that were not readily observed by patients or physicians. Subsequent concerns were burns, crusting, wasting away of the surface lining of the nasopharynx, lesions of dilated small blood vessels, damage to growing bone and soft tissue, and cancer. Reports of thyroid and other carcinomas following treatments with external sources of radiation began appearing from 1950 to 1960, causing concern about the potential for nasopharyngeal radium treatments to cause cancer.

Two studies of children who received nasopharyngeal radium irradiation were published in 1982 and 1989, with conflicting results. The first, by Sandler and colleagues in Maryland, found a statistically significant increase in head and neck tumors including brain tumors (four cases in the exposed group of 904 subjects vs. none in the unexposed comparison group), a statistically non-significant increase in lymphatic-hematopoietic and skin cancers, and a statistically non-significant decrease in breast cancer. The second, by Verduijn and colleagues in the Netherlands, found a statistically non-significant decrease in brain and breast cancers, and a statistically non-significant increase in lymphatic-hematopoietic and other cancers. No head and neck tumors other than brain tumors were found in either the exposed or unexposed groups.

To summarize what is known about possible adverse health effects from nasopharyngeal radium irradiation, the limited studies that have been done are inconclusive with regard to health risk from nasopharyngeal radium irradiation. All of the studies that have been published address only the possible association of various head and neck cancers with nasopharyngeal radium irradiation.

Based on our review of the literature, and preliminary estimations of radiation doses received and of the numbers of subjects necessary, it may be possible to perform a meaningful epidemiologic study of persons who received nasopharyngeal radium irradiation. By this we mean a study with the ability to detect an association between exposure and disease if one truly exists, or the ability to prove no association between exposure and disease if there truly is no association. However, such a study is likely to be difficult and complex. Therefore, it is very important that a feasibility study be undertaken before any resources are committed to a comprehensive study.

If an epidemiologic study were to be conducted, a design known as the retrospective cohort study would probably provide the most information on risks to persons who received nasopharyngeal radium irradiation. Cohort studies can be used to examine a broad array of adverse health effects, which for people exposed to nasopharyngeal radium irradiation would include pituitary and thyroid disease and cancers of the brain, parotid and other salivary glands, pituitary gland, nasal sinus, nasopharynx, soft palate, ard thyroid gland. The retrospective cohort method would involve identifying a group, or cohort, of persons who received nasopharyngeal radium irradiation in the 1940s and 1950s. To determine risks for cancer, the health experience of the cohort of exposed persons would have to be compared with a similar group of persons who did not receive nasopharyngeal radium irradiation. Such a study would take into to account tobacco and alcohol use, which may also cause specific tumors in the head and neck. However, use of the retrospective cohort method could be difficult and complex, because two very large groups would need to be identified and have their health outcomes tracked over the ensuing years until the present.

Issues that would need to be thoroughly addressed to determine whether a study of this subject is feasible would include 1) the ability to identify and trace a cohort of persons who received the treatment in the 1940s and 1950s, and the ability to identify and trace a cohort of people who are similar in all respects except that they did not receive the radium treatment; and 2) the ability to ascertain the medical history of all study subjects during the ensuing 40 to 50 years. Because the expected occurrence of the various types of cancers is relatively small, missing just one or two cases could have a major impact on the results of the study. Therefore, for this study to be useful, it would be ideal to identify all cases of cancer that have occurred in cohort members since the 1940s. Locating living persons from records of 40-50 years ago would be very time intensive and would require the use of a variety of information sources, such as voter lists, driver's licenses, birth certificates, tax and property records, and military records. Determining the health status and possible occurrence of disease in those who are alive and can be located could be done through interviews, extensive reviews of medical records, and complete medical examinations. Determining the health history of those who are deceased and therefore unavailable for interview would clearly be more problematic. Therefore, it would be very important that a feasibility study be undertaken before any resources are committed to a comprehensive study.

As a point of reference, CDC is currently conducting the Hanford Thyroid Disease Study, which is a retrospective study of persons exposed in the 1940s and 1950s to radioactive iodine emissions from the Hanford Nuclear Facility in the state of Washington. To complete this study CDC and its contractor will need to trace, locate, administer a questionnaire to, and examine more than 3,000 individuals. This study is requiring approximately $17 million, three CDC full time positions and 40 contractor staff, and 8 years to complete. The pilot phase of this study has taken two years.

CDC would be willing to provide consultation to the Department of Veterans Affairs and the Department of Defense as they pursue the feasibility of a study of individuals exposed to this treatment during military service. The issue of the use of this treatment in the general population is separate from that of the military and would require a substantial effort to determine feasibility. If an epidemiologic study is indeed feasible, it should be realized it would be a very complex undertaking which would require significant effort and resources that would need to be sustained over a long period.

I would be happy to answer your questions.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Centers for Disease Control
and Prevention (CDC)
Atlanta GA 30333

OCT 26 1994

The Honorable Joseph I. Lieberman
United States Senate
Washington, D.C. 20510

Dear Senator Lieberman:

I am responding to your letter to Dr. James Smith, Chief, Radiation Studies Branch, National Center for Environmental Health, Centers for Disease Control and Prevention (CDC). Enclosed are responses to issues raised in the August 29 hearing on nasopharyngeal radium irradiation before the Subcommittee on Clean Air and Nuclear Regulation.

I appreciate the opportunity to clarify these issues.

Sincerely,

David Satcher, M.D., Ph.D.
Director

Enclosure

RESPONSES BY
THE CENTERS FOR DISEASE CONTROL AND PREVENTION (CDC)
TO QUESTIONS SUBMITTED BY
HONORABLE JOSEPH I. LIEBERMAN
SUBCOMMITTEE ON CLEAN AIR AND NUCLEAR REGULATION
SENATE COMMITTEE ON ENVIRONMENT AND PUBLIC WORKS
U.S. SENATE

QUESTION 1

If a cohort of individuals who received the treatment could be easily and cheaply located, how long would a comprehensive epidemiologic study take to implement?

ANSWER

CDC suggests that a feasibility study first be conducted. The feasibility study would include the compilation of current literature (this has already been completed) and with assistance from Senator Lieberman, identify the private group in New England that has been involved in collecting over 4,000 names, addresses and medical histories of persons, military and civilian, who underwent this treatment. CDC would discuss with this group the information collected as well as contact health officials and others who may have data regarding this treatment. However, resources would be required to explore fully the feasibility of such a study. If proven to be feasible, the steps involved in an epidemiologic study would include:

1. Developing a protocol and data collection instrument(s) --(a questionnaire to ask the individuals and data to be collected from medical records);
2. Obtaining Institutional Review Board (IRB) approval for the study;
3. Submitting for scientific peer review, concurrent with IRB's review;
4. Incorporating changes from IRB and peer review and submitting final protocol and data collection instrument(s) to Office of Management and Budget (OMB) for approval;
5. Identifying and locating a cohort of exposed individuals and a cohort of unexposed individuals;
6. Administering the questionnaire to the individuals and obtaining permission to review medical records;

7. Abstracting relevant information from old medical records regarding nasopharyngeal radium irradiation treatments and from current medical records regarding possible adverse health events;

8. Performing clinical examinations and laboratory tests to identify health problems which have not yet been diagnosed;

9. Entering data into a computer database;

10. Analyzing data; and,

11. Interpreting and reporting results.

Before individuals are identified and traced, peer review, IRB and OMB approval of the study protocol and data collection instrument(s) are required. This approval process usually takes a minimum of 12 to 18 months.

Based on our experience with other studies of individuals exposed to radiation in the 1940s and 1950s, it will be difficult and expensive to trace the current location of those exposed. As a point of reference, CDC is conducting a study of people exposed in the 1940s and 1950s to radioactive iodine emissions from a nuclear facility in Washington State. To complete this major study, more than 3,000 individuals will be traced, located, interviewed, and examined. This study is requiring approximately $17 million, three CDC full-time positions, 40 contractor staff, and 8 years to complete. The pilot phase of this study has taken 2 years. Not all studies will be this complicated and expensive, but a study of nasopharyngeal radium irradiation could be as complex and difficult to conduct as the previous example. This is particularly true since people who received nasopharyngeal radium irradiation are less likely to be concentrated in one State and more likely to be located in many parts of the United States.

QUESTION 2

How should such a study be structured?

ANSWER

The study would be a retrospective cohort study to compare the health experience of a group of exposed individuals with the health experience of a group of unexposed individuals.

QUESTION 3

Who would be the study subjects? (Should it cover veterans and civilians? Should it distinguish between individuals who were treated as children versus individuals who were treated as adults? Should it distinguish between men and women?)

ANSWER

A study of individuals who received nasopharyngeal radium irradiation should treat adults and children separately, and would probably be best conducted as two different studies. This is because of (1) the differing responses of children and adults to radiation and (2) the differing size of adult and children's heads which would affect doses received by other organs. Because military personnel were all adults at the time they received nasopharyngeal radium irradiation and the majority of civilians treated appear to be children, a study could be broken into a study of adult military personnel and a study of civilian children. We do not think men and women respond differently to head and neck radiation, but of course we would collect information on gender and include it in the analysis.

QUESTION 4

What health problems should it cover?

ANSWER

A study could address several health problems: (1) head and neck cancer, including brain, oral and nasopharyngeal, thyroid and other cancers; (2) non-cancer tumors, particularly of the thyroid and pituitary glands; and (3) altered function of the thyroid and pituitary glands. Because thyroid and some other cancers do not have high mortality rates, a study of mortality would miss these cancers, as well as benign tumors and endocrine disorders. Therefore, a morbidity (disease incidence) study would be more appropriate. As more discussion and research are focused on this issue, other health problems may be identified which also need to be included in a study.

QUESTION 5

In your opinion, could the Submarine Survivors Group database provide the basis for such a study?

ANSWER

The Submarine veteran's group is a useful starting point for beginning a search for radium exposed veterans, but a study that relied only on persons who have volunteered information on themselves would not be a scientifically sound basis for determining the incidence of head and neck cancers in radium-exposed veterans. A systematic effort to try to identify all exposed persons or a representative group is needed to accurately determine the incidence of cancer and other diseases.

QUESTION 6

How does the CDC propose to notify civilians who underwent nasopharyngeal radium irradiation of the treatment's potential health effects? What would be CDC's mechanism for notification?

ANSWER

CDC has many forums by which it communicates with the medical community. Most prominent of these is the Morbidity and Mortality Weekly Report (MMWR). The MMWR is published weekly by CDC and contains relevant current information for medical and public health practitioners. The format often contains discussion and recommendations as well as the information on the current topic.

CDC has also initiated discussions with the National Institutes of Health (NIH) to jointly update an advisory concerning head and neck irradiation which NIH first issued in 1977. The NIH advisory could possibly be updated to include more recent published risks from head and neck irradiation.

QUESTION 7

If a health bulletin is used, to whom would it be sent and what would it contain?

ANSWER

A health bulletin could be made available through the offices of physicians and other health care providers. It would contain information on potential harm from all forms of head and neck irradiation.

QUESTION 8

In your testimony before the Subcommittee, you (Dr. Smith) mentioned a 1977 National Cancer Institute (NIH) health advisory regarding the cancer risks from radiation exposure and testified that it might be updated to reflect recent information regarding nasopharyngeal radium irradiation. Please provide a copy of that health advisory and state how it could be updated for reissuance.

ANSWER

Please refer to the enclosure which is a photocopy of the 1977 advisory. We are discussing with our colleagues at NIH how this advisory might be updated.

QUESTION 9

How should CDC's notification efforts be monitored to ensure that they are successful? Please explain what steps CDC is taking or will take to effect such notification.

ANSWER

CDC has initiated discussions with NIH regarding jointly updating an advisory concerning head and neck irradiation, which NIH first issued in 1977. Leaders of professional medical societies and patient groups could also be included in these discussions. Issues being addressed in the discussions include what information could be included in an updated advisory, and what mechanisms could be used to distribute the advisory. To evaluate the distribution of the notification, press reports, wire service reports, and reports in medical journals could be monitored. To monitor whether people take action, a survey of health providers could be performed to determine whether they had examined any patients in response to the notification.

FOR FURTHER INFORMATION

Write to
Office of Cancer Communications
Dept T
National Cancer Institute
Bethesda, Maryland 20014

U.S. DEPARTMENT OF HEALTH,
EDUCATION, AND WELFARE
Public Health Service
National Institutes of Health
National Cancer Institute

DHEW Publication No. (NIH) [illegible]

Did YOU as a child or a young adult have X-RAY TREATMENTS involving your HEAD or NECK ?

X-RAY TREATMENTS AND THYROID CANCER

An Important Message
From The National Institutes
of Health

DID YOU AS A CHILD OR A YOUNG ADULT HAVE X-RAY TREATMENTS INVOLVING YOUR HEAD OR NECK?

IF SO, IT IS IMPORTANT THAT **YOU** HAVE AN **EXAMINATION BY YOUR PHYSICIAN.**

WHY SHOULD YOU BE EXAMINED?

You may now be in a "high risk" group of men and women who have an above average chance of developing tumors of

THE THYROID GLAND at any time from 5 to 30 or more years after such X-ray exposure

Fortunately these tumors are usually slow-growing and benign (noncancerous) They remain confined to the neck for long periods, even when they are cancerous When discovered early, they can be successfully removed

WHAT IS THE THYROID?

It is a gland at the base of the throat It affects your growth development and rate of metabolism

WHY HIGH RISK?

A link recently has been recognized between tumors of the thyroid gland and X-ray treatments administered years before for various noncancerous conditions of the head, neck or upper chest

For several decades beginning in the early 1920 s, radiation therapy was considered good medical practice and effective treatment for conditions including

- ringworm of the scalp
- enlargement of the thymus gland
- deafness due to lymphoid tissue around the Eustachian tubes
- enlargement of the tonsils and adenoids
- acne

Because short-term effects of the treatments appeared to be excellent, thousands of children and young adults in the United States received radiation for these conditions, particularly before antibiotics became available

Unfortunately the thyroid gland also frequently received some radiation during these treatments

WHAT YOU SHOULD DO?

If you think you might have had such X-rays, do not delay. **CONTACT A PHYSICIAN AND ASK HIM TO EXAMINE YOUR THROAT AND NECK.** Then follow up with regular examinations every one to two years. It is important to be examined by a physician, whether or not you can feel any kind of lump in your throat or neck. If you do feel a lump, have it checked out **IMMEDIATELY.**

If your physician finds a tumor, remember—most tumors are **NOT CANCER.**

WHAT DOES THE EXAMINATION CONSIST OF?

The physician will feel the thyroid gla in your neck for any indication of a lum or swelling The exam takes only a few minutes and involves no discomfort

DEPARTMENT OF THE AIR FORCE

PRESENTATION TO THE COMMITTEE ON ENVIRONMENT AND PUBLIC WORKS
SUBCOMMITTEE ON CLEAN AIR AND NUCLEAR REGULATION
UNITED STATES SENATE

SUBJECT: Health Effects of Radium Nasopharyngeal Irradiation

STATEMENT OF: Major General Robert A. Buethe, Jr.
Acting Surgeon General of the Air Force

August 1994

NOT FOR PUBLICATION UNTIL
RELEASED BY THE SENATE
COMMITTEE ON ENVIRONMENT
AND PUBLIC WORKS,
UNITED STATES SENATE

Good morning Mister Chairman and members of the committee. I am Major General Robert A. Buethe, Jr., acting Surgeon General of the United States Air Force. It is my pleasure to be with you this morning to address your concerns regarding radium nasopharyngeal irradiation treatment.

Irradiation of lymphoid tissue in the nasopharynx using radium was widely practiced by physicians in the U. S. beginning in the 1920's and well into the 1960's. This therapy was designed to improve the function of the eustachian tube by shrinking excessive lymphoid tissue in and around the tubal orifice. Hundreds of thousands of civilians were treated; primarily children with recurrent ear infections. The advent of myringotomy tubes led to discontinuation of this therapy.

During WWII a large number of aviators developed a condition known as aerotitis media. Aerotitis media is an inflammation of the middle ear caused by atmospheric pressure changes. Aerotitis media was a problem for the Air Force during WWII due to two main factors (1) rapid pressurization of the middle ear during descent in combat aircraft and (2) high rates of upper respiratory tract infections, particularly during winter months in England and Italy. Some flying personnel experienced this condition on a recurrent basis, leading to subsequent grounding for days to weeks. One report stated that such patients were unavailable for combat duty 30% of the time. Nasal pharyngeal irradiation with radium rods was one treatment option used in these patients. The number of patients treated with radium rods during WWII was approximately 7000. There were a number of other treatment options used prior to considering radium rod therapy. It is important to note that nasopharyngeal irradiation treatments were considered standard of practice at the time and not experimental.

There are no consolidated listings of patients who received radium rod therapy. Some individuals have identified themselves to the Department of Energy's ionizing radiation hot line. In such cases, it may be possible to locate the serviceman's medical records and confirm the treatment.

It is our intention to fully support any efforts by the Department of Veterans' Affairs to study any medical complications which may be associated with this form of therapy.

RESPONSES TO POST-HEARING QUESTIONS FROM SENATOR LIEBERMAN

Senator Lieberman: I understand that documents exist which indicate that over 8,000 servicemen were treated during World War II with nasopharyngeal irradiation. The Submariner Survivors Group has conducted research which indicates that approximately 10,000 Navy personnel and 25,000 Army Air Force personnel were treated. In addition, it has been estimated that approximately 10,000 dependents underwent this treatment.

How long will it take for DoD to search its records to identify veterans and veterans' dependents who underwent this treatment? Does DoD have a plan of action for conducting an expedited search for records of targeted groups of veterans?

General Buethe: As indicated in my testimony, there is no consolidated listing of individuals who received nasopharyngeal irradiation. Such treatments would have been recorded in the patient's medical record in the same manner in which any medical procedure would be recorded. These records are stored at the National Personnel Records Center in St. Louis and number in the millions. There is no practical way to search this massive number of records. With regard to searching for records of targeted groups of veterans, we have pledged to assist the Department of Veteran's Affairs (DVA) in identifying and obtaining records of these targeted groups. Our plan would include engaging the Air Force Historical Research Agency and the Center for Air Force History to assist in locating historical records which might list the names of individuals assigned to the bases which offered nasopharyngeal irradiation. These names would be provided to the DVA which would then undertake a location and notification process.

Senator Lieberman: For the DoD records that are found indicating that veterans or veterans' dependents received this treatment, how does the DoD propose to notify those individuals of the treatment's potential health effects? How does DoD's plan to ensure that the notification efforts are successful? Please specify all steps the DoD is taking or is planning to take to effect such notification.

General Buethe: Since the majority of patients who received this treatment were not veterans or veterans' dependents, any notification efforts which are deemed appropriate should be directed towards the population at large. As indicated in the testimony, the Center for Disease Control (CDC) has responsibility for notifying health care personnel of disease or treatment risks. The success of any large scale notification effort is dependent on ensuring the information is widely disseminated. We are prepared to support the efforts of CDC by working with the DVA in contacting veterans' groups.

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COMMITTEE ON
ENVIRONMENT AND
PUBLIC WORKS

STATEMENT OF

REAR ADMIRAL HAROLD M. KOENIG, MEDICAL CORPS

DEPUTY SURGEON GENERAL

UNITED STATES NAVY

AUGUST 29, 1994

BEFORE THE

SUBCOMMITTEE ON CLEAN AIR AND NUCLEAR REGULATION

OF THE

SENATE COMMITTEE ON ENVIRONMENT AND PUBLIC WORKS

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THE SENATE
COMMITTEE ON
ENVIRONMENT AND
PUBLIC WORKS

STATEMENT
OF
REAR ADMIRAL H. M. KOENIG
BUREAU OF MEDICINE AND SURGERY
AUGUST 29, 1994

Good Morning, Mr. Chairman.

Thank you for the opportunity to appear here today to answer questions about nasopharyngeal irradiation medical treatment of former members of the U.S. Navy, and its possible association with an increased incidence of health problems.

The medical procedure for nasopharyngeal irradiation with radium applicators was developed in the late 1920's at Johns Hopkins University. It proved to be an extremely effective mode of treatment that became widespread, and is credited through the 1930's to the 1960's with preventing deafness in many children suffering from otitis media. As many parents know, small children still suffer from this ailment. Today's treatment methods employ antibiotics and the implanting of drainage tubes through the tympanic membrane of the ear.

During World War II, a sizeable percentage of submarine volunteers were experiencing aerotitis media, also called middle ear barotrauma, or more simply, a problem resulting from failure to equalize differential pressure across the eardrum, while completing submarine escape training. For submarine candidates, this was a disqualifying condition.

Radium irradiation of lymphoid tissue surrounding the opening of the eustachian tube which connects the inner ear with the nasal passages offered a cure: it did not involve surgery; it could be performed in a doctor's office; and it produced minimal side effects and did not require recuperation time. It was an accepted treatment method that was widely used to improve inner ear drainage in the civilian medical community throughout the 1940s.

In your recent letter of August 18, 1994 to Secretary Perry, you asked how many Navy men received nasopharyngeal irradiation treatment with radium applicators. That question cannot be answered at this time. We know that a Navy study published in the medical literature in 1946 compared the treatment of 732 submariners with radium applicators to other treatment methods, and the study clearly showed that this form of treatment was the most effective. The authors of a 1992 letter to New England Journal of Medicine estimated up to 5,000 submariners may have received this treatment. We do not have any factual listing of the number of subjects treated to confirm or alter this estimate.

Your letter also raised the question as to the degree of details provided in informing patients about this treatment. We are unable to definitively state what occurred nearly fifty years ago in doctors' offices. The procedure would have been explained to them, and likely they would have been told that it was a safe treatment, although uncomfortable, and that no adverse effects were expected from the radiation exposure.

For an epidemiological study to produce findings which have validity in dealing with cancer incidence rates, it is necessary to identify those who had received treatment and a similar cohort who had not received the radium treatment. Currently, with the exception of about 19 names, we have been unable to find patient identification data for those that may have received radium nasopharyngeal treatment. Our searches this year have included the files at Groton, CT and the archives at the Personnel Record Center at St. Louis, MO. A search of medical records that could be found of those 19 names failed to show documentation that they had received radium nasopharyngeal treatments. It is not clear why the medical records do not contain documentation of the radium treatments.

Mr. Chairman, it is the Navy's desire to assist you in addressing health questions that have been raised. We will work closely with the Department of Veterans Affairs in investigating this question and will support their efforts in any follow-on epidemiological study.

That concludes my statement Mr. Chairman. I will be happy to answer any questions you may have at this time.

SENATE COMMITTEE ON ENVIRONMENT AND PUBLIC WORKS
SUBCOMMITTEE ON CLEAN AIR AND NUCLEAR REGULATIONS
HEARING ON: HEALTH CARE REFORM BILL
29 AUGUST 1994
QUESTION NUMBER 1

DOD RECORDS

Senator Lieberman: I understand that documents exist which indicate that over 8,000 servicemen were treated during World War II with nasopharyngeal irradiation. The Submarine Survivors Group has conducted research which indicates that approximately 10,000 Navy personnel and 25,000 Army Air Force personnel were treated. In addition, it has been estimated that approximately 10,000 dependents underwent that treatment.

How long will it take for DOD to search its records to identify veterans and veterans' dependents who underwent this treatment? Does DOD have a plan of action for conducting an expedited search for records of targeted groups of veterans?

RADM Koenig: The Navy does not have documents that tell us how many veterans and veterans' dependents received that radium nasopharyngeal treatment. Although the Navy has conducted an extensive search of its files to try to locate logs or other records that would identify treated submariners, such records have not been found and are presumed destroyed. The search included both on-site and archived files of the Naval Hospital Groton, Submarine Medical Center, Naval Medical Research Laboratory and Naval Undersea Medical Institute, all in Groton CT. From Dr. Haines' 1946 published study we know that he treated 732 submarine candidates (name unknown) as part of a comparative study, and that due to the efficacy of the treatment for aerotitis media, the treatment was subsequently utilized in an unknown number of submarine candidates. Numbers treated are estimates not based on any written record.

This treatment should have been documented in the medical record. The Navy reviewed the medical records of a small number of servicemen who were believed to have a high probability of having received the treatment. None of the records documented the treatment. The VA is presently reviewing the medical records of a group of veterans who self identified themselves to the Submarine Survivors Group as having received the treatment. The results are important because written documentation is needed to confirm the treatment and allow determination of the dose delivered. Without documentation in the medical record, Navy has no way to identify or confirm which individuals were treated.

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SENATE COMMITTEE ON ENVIRONMENT AND PUBLIC WORKS
SUBCOMMITTEE ON CLEAN AIR AND NUCLEAR REGULATIONS
HEARING ON: HEALTH CARE REFORM BILL
29 AUGUST 1994
QUESTION NUMBER 2

DOD NOTIFICATION EFFORTS

Senator Lieberman: For the DOD records that are found indicating that veterans or veterans' dependents received this treatment, how does the DOD propose to notify those individuals of the treatment's potential health effects? How does DOD plan to ensure that the notification efforts are successful? Please specify all steps the DOD is taking or is planning to take to effect such notification.

RADM Koenig: Based on its extensive records search to date, the Navy is no optimistic that records will be found that document, by name, those individuals that received this treatment. Consequently, plans have not yet been developed to notify individuals. Even if not clear whether it would be feasible to conduct a targeted search among the millions of medical records at the National Personnel Records Center, St. Louis. Since many more civilians were treated than military, the Navy believes that any notification efforts deemed appropriate should be directed toward the population at large. From Senator Lieberman's hearing we understand that the CDC is investigating the need for such a notification or health advisory. We are prepared to assist the CDC in any way we can as it studies this issue.

STATEMENT OF:
David Miller
Burlington, Vermont

PRESENTED TO:
United States Senate
Subcommittee on Clean Air and Nuclear Regulation

September 14, 1994
(For August 29, 1994 Hearing)

My name is David Miller. I am 47 years old and am a resident of Burlington, Vermont. My story begins with ear and tonsil infections at an early age, when on two separate occasions my tonsils and adenoids were surgically removed. When this course of action failed to resolve the infection, our family doctor recommended taking me to another physician who practiced on Colchester Avenue in Burlington. A number of nasal irradiation procedures were carried out at this location.

Almost immediately after I received the nasal irradiation treatments, other infections manifested themselves. My parents response would be, "You had those treatments. You're alright. Gargle with salt and water." At puberty issues appeared which I am sure were directly related to nasal irradiation. From the time I had the procedure to adulthood, I was given poor health care by my family.

After reading Mr. Stewart A. Farber's testimony of August 29, I knew I had found an ally. The digestive problems I have experienced since the nasal irradiation, as well as chronic infection, as of late two years ago requiring a hospital stay of five days (no wound could be found to cause the infection) seem to point in one direction.

Being the father of three children, one of which was born with minor birth defects, is a legitimate concern. With the help of many friends, periodicals, reports and books, a special diet, all of which have exhausted my financial reserves, I've strengthened my immune system and am getting along. However, emotional issues, employability are considerations that will have to be dealt with. We affected should be VIGILANT and exercise the virtue of FORTITUDE.

Thank you for this opportunity.

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